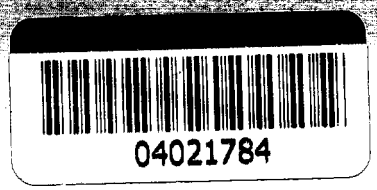
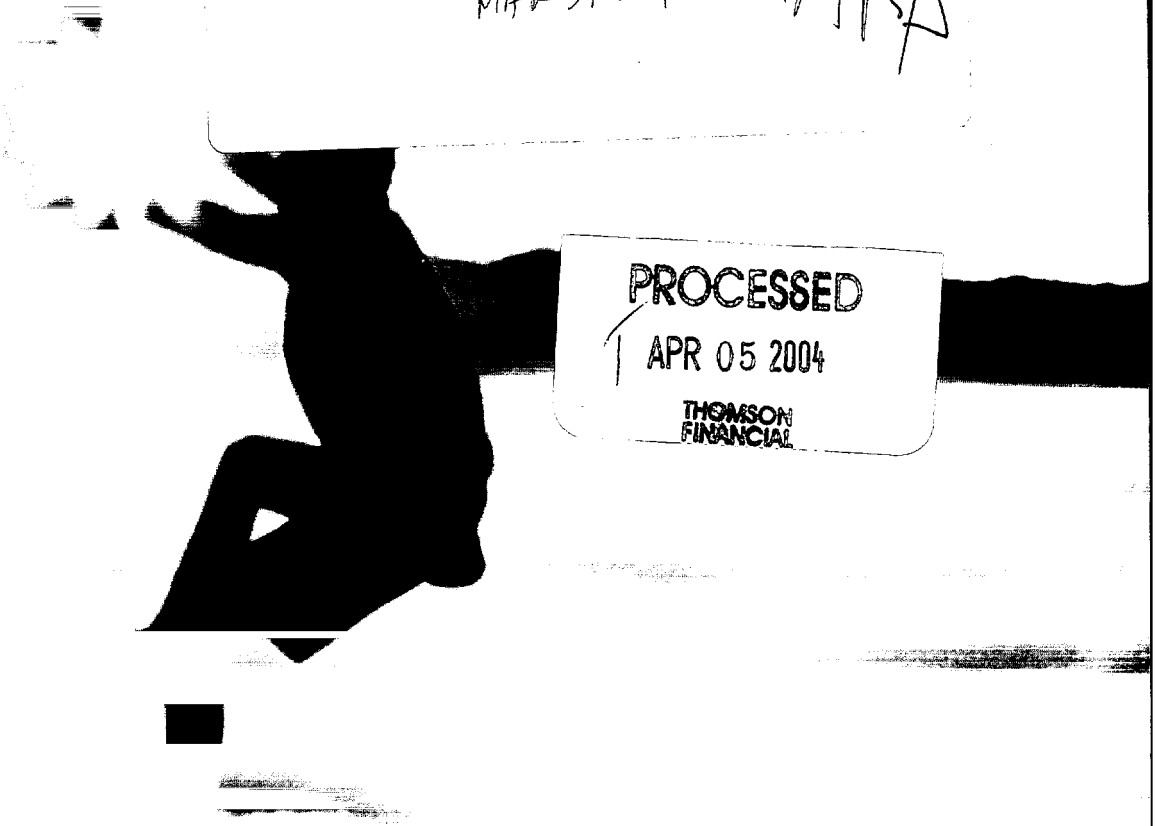
IVAX

IVAX PHARMACEUTICALS INCORPORATED ANNUAL REPORT 2003



ACHIEVEMENT & OPPORTUNITY



EVERY GREAT JOURNEY STARTS WITH ONE STEP.

The approval of Plenaxis™ represents years of dedication to drug discovery and development at PRAECIS to bring an innovative product to the market and marks an important milestone in our transition to a fully integrated pharmaceutical company.

For full prescribing information, visit www.plenaxis.com.

MALCOLM L. GEFTER, PH.D.

CHAIRMAN OF THE BOARD AND
CHIEF EXECUTIVE OFFICER

TO OUR STOCKHOLDERS:

The year was marked by significant achievement and the emergence of new opportunities for PRAECIS. In November 2003, we reached one of the most significant milestones in the history of PRAECIS when the United States Food and Drug Administration (FDA) granted approval of our drug Plenaxis™ for the treatment of a subset of men with advanced prostate cancer. With this approval, we are poised to capitalize on both the commercial opportunity that Plenaxis™ represents and our ability, now validated, to turn scientific discovery into commercial reality.

ACHIEVEMENT

The approval of Plenaxis™ is a great achievement. It is the first step in our mission of translating scientific discovery into commercial reality, both effectively and efficiently.

The approval of Plenaxis™ also validates the scientific approach of our core LEAP™ technology. LEAP™ technology was utilized in the development of Plenaxis™ and is characterized by its ability to identify drug candidates from extremely large libraries of molecules in a more efficient manner than traditional methods of drug discovery. LEAP™ technology was also utilized in the development of Apan™, our investigational drug candidate for the treatment of Alzheimer's disease. Recently, we announced that we have advanced our technology platform to allow us to select drug candidates more efficiently and in greater numbers. We have named this enhancement Direct Select™ Technology and we believe that it will support our tactical approach to drug discovery. We believe that better drugs emerge from a process that includes selecting from large numbers of candidate molecules versus a process where molecules are optimized through complex engineering.

OPPORTUNITY

The approval of Plenaxis™ ushers in a new chapter in the evolution of PRAECIS. We are now a fully integrated biopharmaceutical company with capabilities spanning drug discovery, clinical development, manufacturing and commercialization.

We do not view the approval of Plenaxis™ as a resting place. Instead, the approval marks a turning point where new and undiscovered opportunities await PRAECIS and its stockholders. Several attributes of the Plenaxis™ opportunity make it an especially well suited first product launch for PRAECIS. First, Plenaxis™ is the result of internal development and its value is owned entirely by PRAECIS. Second, Plenaxis™ is a well-differentiated product when compared to existing therapies and therefore represents an exciting commercial opportunity. Importantly, the Plenaxis™ opportunity is focused on a


AVAILABILITY

defined specialist audience of urologists/oncologists – readily approachable by a smaller, more targeted sales team. This, together with the very specific patient population for which Plenaxis™ is indicated, translates into an efficient, targeted marketing program with respect to the launch of this product. Accordingly, during the past twelve months we have been developing a commercial organization and launch strategy that we believe will maximize the value of this opportunity. As we continue to build out this focused commercialization infrastructure for Plenaxis™, we are confident that our new commercial capabilities can be leveraged in the future to bring other urology/oncology products to market.

With regard to the commercialization efforts for Plenaxis™, we are gaining appreciable traction in our sales and marketing efforts. Since January 2004, Plenaxis™ has been available across the country to physicians and hospital pharmacies enrolled in the Plenaxis™ User Safety (PLUS) Program. At this writing, we have substantially completed the hiring and training of our 50 person field force. With an average of approximately six to eight years of experience, this well-seasoned team is already providing urologists and oncologists with significant insight into the appropriate use of Plenaxis™.

PLUS™
Plenaxis™ (abarelix for injectable suspension) User Safety Program

To complement our sales effort, we are carrying out a variety of important marketing initiatives and are leveraging our key opinion leader support through a host of educational programs in the United States. In addition, we are planning to have a significant presence at the upcoming annual meetings of both the American Urological Association (AUA) and the American Society of Clinical Oncologists (ASCO).

We also initiated the regulatory review process for Plenaxis™ in the European Union during 2003 with the submission of a Marketing Authorisation Application (MAA) in Germany seeking approval for the treatment of a broad population of hormonally responsive prostate cancer patients. Assuming a favorable action on our application, we plan to pursue further European Union approval under the Mutual Recognition Procedure. We intend to commercialize Plenaxis™ in Europe, Japan and other territories outside of the United States through corporate partners. We expect to announce the details of a European partnership in 2004.

Since January 2004, Plenaxis™ has been available across the country to physicians and hospital pharmacies enrolled in the Plenaxis™ User Safety (PLUS) Program.

CLINICAL PIPELINE UPDATE

During 2003, we also made progress in our clinical programs as we advanced one drug candidate from a Phase Ia to a Phase Ib clinical trial, and initiated a Phase I clinical trial for a new drug candidate. Clinical highlights for 2003 include the following:

- In March, we completed our Phase Ia clinical study of Apan in healthy volunteers and in June, initiated a Phase Ib clinical study of Apan in Alzheimer's patients.

- In April, we filed an Investigational New Drug application for PPI-2458 allowing us to initiate, in late 2003, a Phase I clinical study of PPI-2458 in non-Hodgkin's lymphoma (NHL) patients. (In March 2004, the FDA placed this trial on clinical hold due to an unexpected preclinical finding. We are currently evaluating this finding and we will submit a detailed plan to the FDA in order to address the finding and gain FDA approval to restart clinical testing.)

- In December, we announced a collaboration with the National Cancer Institute's Division of Cancer Treatment and Diagnosis for the expansion of clinical development of PPI-2458 in various forms of cancer. The opportunity for the NCI to pursue activities related to PPI-2458 will become available once FDA approval to restart clinical trials has been granted.

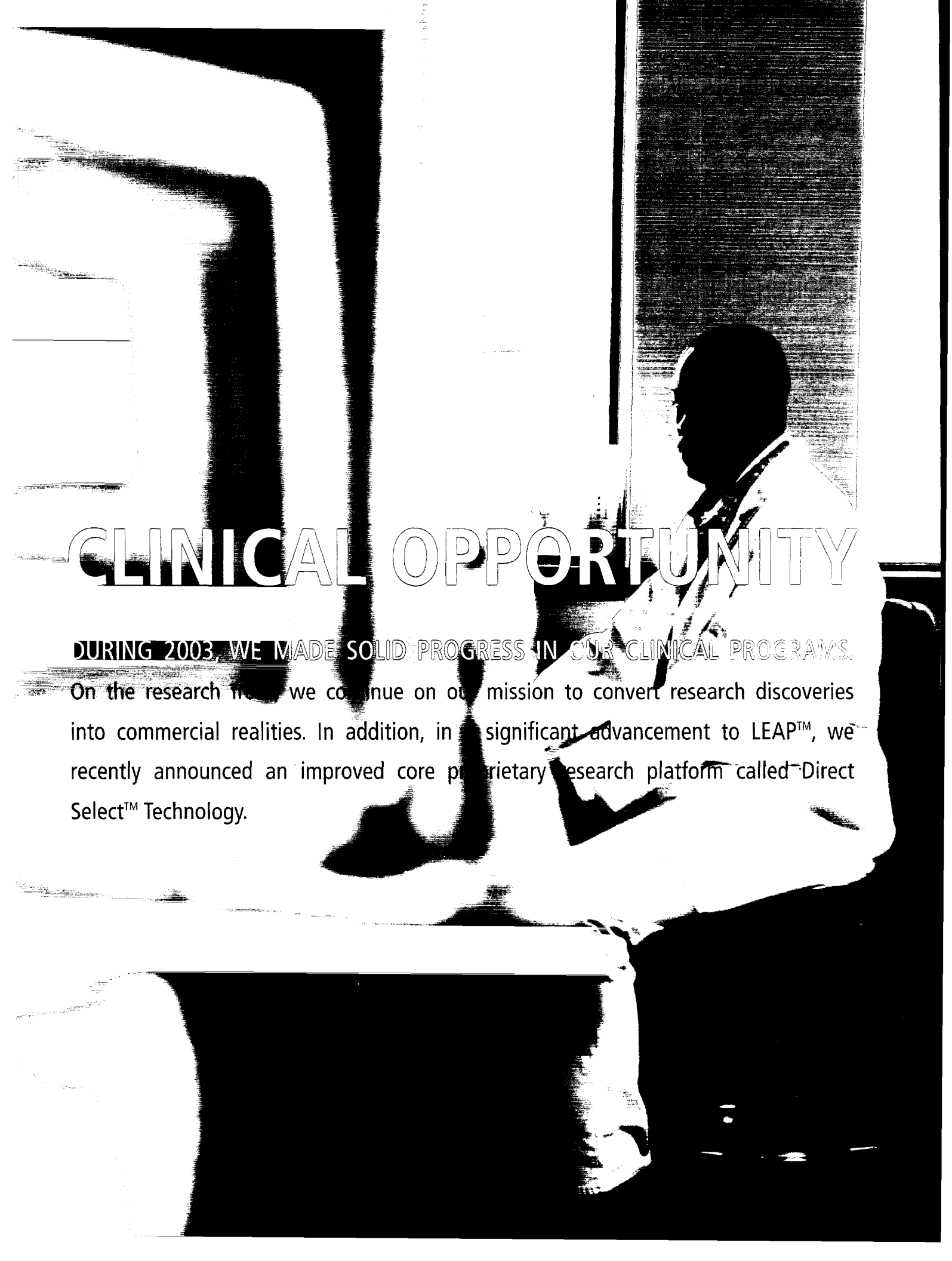
APAN FOR ALZHEIMER'S DISEASE

It is believed that Alzheimer's disease results from the accumulation of beta-amyloid in brain tissues. We believe Apan is one of the most advanced therapeutics in clinical testing that is designed to alter this accumulation and thus change the course of the disease. The cost of Alzheimer's disease to the U.S. healthcare system has been estimated to be approximately $100 billion annually. Consequently, we believe that if our clinical program is successful, Apan could well be a valuable treatment for many in the large and growing population affected by this debilitating disease.

The clinical program for Apan continues to progress. We determined a maximum tolerated dose (MTD) for Apan administration in our Phase Ia trial in healthy volunteers and in June 2003, initiated a Phase Ib clinical study in affected patients. In this dose escalation study, a single dose of Apan is administered, with the goal of determining the MTD in patients. We anticipate completing this study during the first half of 2004. Shortly thereafter, assuming favorable FDA review of the study results, we anticipate initiating a Phase Ic study in which the safety of giving multiple doses of Apan to Alzheimer's patients will be evaluated.

PPI-2458 FOR NON-HODGKIN'S LYMPHOMA

PPI-2458, our proprietary methionine aminopeptidase type-2 (MetAP2) inhibitor, is designed for the treatment of certain cancers and autoimmune diseases. PPI-2458 is a novel, proprietary molecule based on the fumagillin class of compounds that have been shown to prevent both abnormal cell growth and the formation of new blood vessels. In late 2003, we initiated a Phase I dose escalation



CLINICAL OPPORTUNITY

DURING 2003, WE MADE SOLID PROGRESS IN OUR CLINICAL PROGRAMS.

On the research fr[illegible] we co[illegible]nue on ou[illegible] mission to convert research discoveries into commercial realities. In addition, in [illegible] significant advancement to LEAP™, we recently announced an improved core p[illegible]rietary [illegible]esearch platform called Direct Select™ Technology.


BIOMARKER DISCOVERY

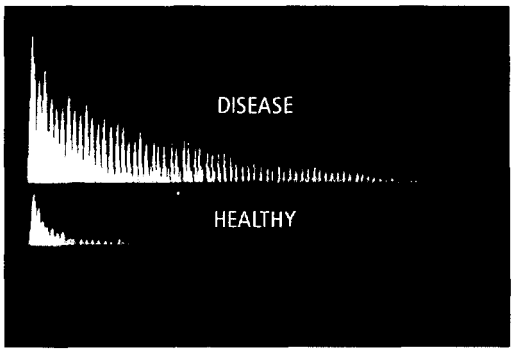
study designed to determine the MTD of orally administered PPI-2458 in NHL patients. In this study, we have utilized a proprietary assay developed to examine MetAP2 inhibition. Initial results have confirmed that orally dosed PPI-2458 is achieving inhibition of its molecular target, MetAP2, in humans. As of March 2004, the use of PPI-2458 in human clinical trials has been placed on clinical hold by the FDA. While we are disappointed with this development, patient safety comes first and clinical holds are not uncommon occurrences in drug development. The Company, together with the FDA, will endeavor to establish a plan to move forward with PPI-2458 in the clinic.

In addition to non-Hodgkin's lymphoma, we also intend to continue evaluating the potential utility of PPI-2458 for treating certain other cancers, as well as certain autoimmune diseases, such as rheumatoid arthritis. Following release of the clinical hold, our collaboration with the National Cancer Institute is intended to expand the clinical evaluation PPI-2458 in multiple oncology indications.

RESEARCH UPDATE

On the research front, we continue on our mission to convert research discoveries into commercial realities. During 2003, we made progress in this respect by validating our proteomics-based Biomarker Discovery Platform with the identification of proteins whose relative abundance is a signature of endometriosis. We are now planning to further assess this finding in a broader population. If successful, we believe that this discovery will serve as the foundation for a commercially viable non-invasive diagnostic test for endometriosis for use in a specialty-testing laboratory environment.

In addition, as noted above, in a significant advancement to LEAP™, we recently announced an improved core proprietary research platform called Direct Select™ Technology. Direct Select™ Technology is an advancement to our ability to generate vast pharmaceutical libraries and will assist us in more rapidly and directly identifying leads with higher affinity and specificity than has been routinely possible using traditional drug discovery methods or with LEAP™. We believe this will result in our ability to choose compounds with the highest potency and the least toxicity for our clinical programs.



During 2003, we validated our proteomics-based Biomarker Discovery Platform with the identification of proteins whose relative abundance are a signature of endometriosis.

FUTURE GOALS

Based upon our commitment to capitalize on the renewed opportunities before us, the following are highlights of our expectations for the future:

Profitability

- We expect to obtain profitability driven by sales of Plenaxis™ by 2006.

The Plenaxis™ Opportunity

- With respect to the future prospects for Plenaxis™, the market for currently available hormonal therapies to treat prostate cancer is approximately $1.2 billion in the United States. We believe that the long-term revenue opportunity for Plenaxis™ may represent 15% or more of this market;

- We expect regulatory action on Plenaxis™ in Germany during the second half of 2004, and to initiate and complete the Mutual Recognition Procedure for the remaining European member states during 2005;

- We expect to conclude a European partnership agreement for Plenaxis™ during 2004; and

- We are continuing to evaluate the potential utility of Plenaxis™ in other indications to further exploit its unique mechanism of action. As part of this process, we have established several groups of experienced clinical advisors and we continue to work closely with these groups of experts to identify indications where the use of Plenaxis™ may provide innovative advantages compared to existing therapies.

Clinical Opportunity

- We expect to complete the Phase Ib clinical trial and to initiate a Phase Ic clinical trial in our Alzheimer's disease clinical program during 2004; and

- We intend to work closely with the FDA to release the clinical hold and resume our non-Hodgkin's Lymphoma clinical program.

On behalf of our Board of Directors and employees, I would again like to thank our stockholders for their support during the past year. We hope that our stockholders will both share in our pride regarding the significance of the approval of Plenaxis™ and look forward to the many opportunities available to PRAECIS during 2004 and beyond.

Sincerely,

Malcolm L. Gefter

Malcolm L. Gefter, Ph.D.
Chairman of the Board and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 000-30289

PRAECIS PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**04-3200305**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
830 Winter Street Waltham, Massachusetts	**02451-1420**
(Address of principal executive offices)	(Zip code)

(781) 795-4100

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

(Title of Class)

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $.01 per share

(Title of Class)

Preferred Stock Purchase Rights

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☒ No ☐

The aggregate market value of voting and non-voting stock held by non-affiliates of the registrant, based upon the last sale price of the common stock, par value $.01 per share, reported on The Nasdaq National Market on June 30, 2003, was $240,343,790.

The number of shares of common stock, par value $.01 per share, outstanding as of February 29, 2004 was 52,191,092.

Documents Incorporated By Reference

Specified portions of the definitive Proxy Statement with respect to the registrant's 2004 Annual Meeting of Stockholders to be filed by the registrant with the Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K.

Factors That May Affect Future Results

The Company's prospects are subject to certain uncertainties and risks. This Annual Report on Form 10-K also contains certain forward-looking statements within the meaning of the federal securities laws. The Company's future results may differ materially from its current results and actual results could differ materially from those projected in the forward-looking statements as a result of certain risk factors. READERS SHOULD PAY PARTICULAR ATTENTION TO THE CONSIDERATIONS DESCRIBED IN THE SECTION OF THIS REPORT ENTITLED "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS—RISK FACTORS THAT MAY AFFECT FUTURE RESULTS." Readers should also carefully review the risk factors described in the other documents the Company files from time to time with the Securities and Exchange Commission.

PRAECIS PHARMACEUTICALS INCORPORATED

ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. BUSINESS.

Overview

We are a biopharmaceutical company focused on the discovery and development of innovative therapies to address unmet medical needs. In November 2003, we received FDA approval to market our first product, Plenaxis (abarelix for injectable suspension), in the United States for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration. We are promoting Plenaxis in the United States through our own marketing and sales team. We have also initiated the regulatory review process for Plenaxis in the European Union with a submission in Germany in June 2003. We expect an action by the German regulatory authorities during 2004 and, assuming it is favorable, plan to pursue further European Union approval under the Mutual Recognition Procedure to market Plenaxis for the treatment of hormonally responsive prostate cancer. We are in discussions with potential partners for the commercialization of Plenaxis in Europe and the development and/or commercialization of Plenaxis in Japan and other areas of the world.

We are also developing Apan, our investigational drug candidate for the treatment of Alzheimer's disease. Apan is designed to treat what we and others believe to be the underlying cause of Alzheimer's disease, rather than the symptoms. A hallmark of Alzheimer's disease is the accumulation of plaque-like deposits in brain tissue. A major component of this plaque is a small peptide called beta-amyloid. Results of our preclinical studies suggest that Apan may be facilitating the clearance of beta-amyloid from the brains of guinea pigs and transgenic mice. In March 2003, we completed a phase Ia dose escalation study of Apan in healthy volunteers. In this study, we evaluated the safety and pharmacokinetics of the compound and identified a maximum tolerated dose, or MTD, in healthy volunteers. In June 2003, we initiated a phase Ib trial in Alzheimer's patients. In this study, a single dose of Apan is administered, with the goal of establishing the MTD in patients. We anticipate completing the phase Ib study during the first half of 2004. Upon completion, and assuming favorable FDA review of the study's results, we expect to initiate a phase Ic trial examining the safety of multiple administrations of a selected dose of Apan in Alzheimer's patients.

During 2003, we filed an investigational new drug application, or IND, for PPI-2458, a novel, proprietary molecule that is based on the fumagillin class of compounds. This class of compounds has been shown to prevent both abnormal cell growth and the formation of new blood vessels (known as anti-angiogenesis), which contribute to the growth of aberrant tissues in diseases such as cancer and rheumatoid arthritis. In December 2003, we initiated an open-label phase I dose escalation study in non-Hodgkin's lymphoma patients. In March 2004, the FDA placed this trial on clinical hold until questions relating to a finding in a recently completed three-month animal safety study have been satisfactorily resolved. The results of this study were not available at the time that the clinical study was initiated. The finding consisted of a neuropathological abnormality in some of the animals tested, similar to findings reported in connection with certain other approved products. In discussions, the FDA indicated that we will need to submit a detailed plan in order to address this finding. These discussions were confirmed in a letter recently received by the Company. We intend to further explore this finding, with input from leading experts as appropriate, to assess its potential implications and prepare a plan for the FDA.

We have also developed the foundation for a potentially simple, non-invasive endometriosis diagnostic test based on the presence of unique proteins in the serum of disease sufferers. Considering that an estimated 5.5 million females in the United States and Canada suffer from endometriosis, and that only approximately 300,000 females in the United States and an unknown number in Canada are actually diagnosed with the disease, we believe a diagnostic test is critical to better identify, assess and treat those who suffer from the disease. Using our proteomics-based Biomarker Discovery Platform, we have identified proteins whose abundance in serum can discriminate between diseased and non-diseased individuals. These proteins could also enhance understanding of the disease process. We

have developed a clinically relevant diagnostic test which can be performed on a commercially available platform. This will allow for the implementation and further clinical assessment of our findings in a broad population. If the findings hold, we believe that this test could be available in a specialty testing laboratory environment on an expedited timetable.

In addition to our clinical programs, we have numerous programs in the research or preclinical development stage. We are focusing our discovery efforts on opportunities in the areas of oncology, inflammation and infectious diseases.

Our proprietary drug discovery technology called Ligand Evolution to Active Pharmaceuticals, or LEAP, has been valuable in the development of our pipeline of product candidates, particularly with respect to Plenaxis and Apan. LEAP technology enables the identification of drug candidates from extremely large libraries of molecules in a more efficient manner than traditional methods of drug discovery. Recently, we announced that we have advanced the scientific approach behind LEAP technology, with a platform we have named Direct Select Technology. This novel technology is an enhancement which should allow us to generate vast pharmaceutical libraries and more rapidly and directly identify leads with higher affinity and specificity than before, and will serve as the foundation for our future drug development projects. We have several granted foreign patents, as well as pending patent applications in the United States and abroad, that cover the essential steps of the LEAP process. In addition, we have filed patent applications in the United States covering the essential steps of the Direct Select process and also intend to pursue patent protection abroad.

Our technology platform also includes a proprietary drug delivery system known as Rel-Ease. Plenaxis is formulated in Rel-Ease, which allows it to be administered to prostate cancer patients once every four weeks. We have demonstrated that Rel-Ease is also useful for formulating various other molecules in sustained release formulations. We hold patents that cover the general application of this technology for a broad range of peptide-based drugs.

We were incorporated in Delaware in July 1993 under the name Pharmaceutical Peptides, Inc. In June 1997, we changed our name to PRAECIS PHARMACEUTICALS INCORPORATED. Our corporate headquarters and research facility is located in Waltham, Massachusetts. We conduct our business in one business segment. For the years ended December 31, 2001 and 2002, substantially all of our revenue was derived in the United States. We did not have any revenue for the year ended December 31, 2003. Long-lived assets consist primarily of property and equipment and are located solely in the United States for all periods presented.

PRAECIS™, Plenaxis™, Apan™, LEAP™, Direct Select™, Rel-Ease™, MASTRscreen™ and the PLUS Program™ are trademarks or trade names of our Company. This Annual Report on Form 10-K also contains trademarks, trade names and service marks of other companies, including but not limited to Casodex®, Eligard®, Lupron Depot® and Zoladex®, all of which are the property of their respective owners.

Approved Product

In November 2003, we received FDA approval to market our lead product, Plenaxis (abarelix for injectable suspension) in the United States. Plenaxis is the first gonadotropin releasing hormone (GnRH) antagonist available as a depot formulation. Plenaxis is indicated for the palliative treatment of men with advanced symptomatic prostate cancer, in whom LHRH agonist therapy is not appropriate and who refuse surgical castration, and have one or more of the following: (1) risk of neurological compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia. Plenaxis is not indicated for use in women or children. For safety reasons, Plenaxis is approved with marketing restrictions under 21 CFR 314, Subpart H, and will be available only to physicians who enroll in the PLUS (PLenaxis User Safety) Program. FDA approved full prescribing information for Plenaxis is available at *www.plenaxis.com.*

In January 2004, we began shipping Plenaxis to our authorized distributors. We are promoting Plenaxis to physicians, primarily oncologists and urologists, through our own dedicated marketing and sales team.

Background. Prostate cancer is one of the most commonly diagnosed cancers in men. The American Cancer Society estimates that approximately 231,000 new diagnoses of, and 30,000 deaths from, prostate cancer will occur in the United States in 2004. Prostate cancer cells require hormones, specifically testosterone and its derivatives, for growth. These hormones stimulate the growth of the cancerous cells. The primary goal of treatment is to reduce testosterone to low, or castrate, levels, leading to inhibition of prostate cancer cell growth. Available treatments for prostate cancer patients include hormonal therapies, radiation therapy and surgery.

Currently available hormonal therapies, known as LHRH agonists, act by overstimulating the GnRH receptor, located on the pituitary gland, a small gland in the center of the brain. Overstimulation of the pituitary GnRH receptor causes the GnRH receptor to become non-responsive after approximately three weeks. However, this overstimulation first leads to increased production of two hormones, luteinizing hormone, or LH, and follicle stimulating hormone, or FSH. The increased level of LH causes an initial surge of testosterone from the testes. The temporary surge in hormone levels may result in an exacerbation of symptoms, or clinical flare, in some patients. Only after several weeks following administration of these hormonal therapies does the GnRH receptor become non-responsive and the desired reduction of hormone levels occurs. Due to this surge, LHRH agonists, such as Lupron Depot, marketed by TAP Pharmaceutical Products Inc., and Zoladex, marketed by AstraZeneca Pharmaceuticals L.P., have precautionary labeling about the hormone-induced flare and resulting worsening of clinical symptoms in some patients. In contrast, Plenaxis has a blocking, or antagonist, effect on the GnRH receptor. Plenaxis reduces levels of testosterone with no initial surge.

For some advanced symptomatic prostate cancer patients, whose disease has progressed, the use of currently available hormonal therapies may not be appropriate. In these patients, the testosterone surge may lead to an exacerbation of symptoms, which could include urinary blockage, worsening pain, kidney failure, paralysis and nerve damage due to spinal cord compression, or, in rare instances, death. For these patients, removal of the testes, known as surgical castration, may be the only treatment option available to rapidly reduce testosterone levels and avoid the testosterone surge, and this option is not always an acceptable one for the patient. Plenaxis offers the first non-surgical alternative approved for these patients.

Clinical Experience in Indicated Population. The use of Plenaxis was studied in 81 patients with advanced symptomatic prostate cancer who were at risk for clinical exacerbation (clinical flare) if treated with an LHRH agonist in an open-label, multicenter, uncontrolled, single-arm study. The primary endpoint of this study was the avoidance of surgical castration at 4 and 12 weeks of treatment. No patient required surgical castration through 12 weeks of Plenaxis treatment, or through 40 weeks (median study duration) in a follow-up study. Specific clinical outcomes in those experiencing symptoms from advanced prostate cancer were also evaluated, although these evaluations were not the primary objective of the study. None (0) of 8 patients with vertebral or epidural metastases and without neurological symptoms developed neurological symptoms. Ten of 13 patients with bladder outlet obstruction and a bladder drainage catheter had relief of their obstruction leading to catheter removal by 12 weeks. Eleven of 15 patients with pain due to skeletal metastases were able to reduce the potency, dose and/or frequency of narcotic analgesia at 12 weeks.

Three of 81 patients withdrew from the study because of an immediate-onset systemic allergic reaction, all of which occurred within minutes of receiving Plenaxis. One patient exhibited hives, another exhibited hives and itching, and the third exhibited transient lowering of blood pressure and fainting. Other reasons for withdrawal from Plenaxis treatment included adverse events, voluntary withdrawal and death due to progressive prostate cancer. The most frequent adverse events (without regard to causality) resulting from (1) Plenaxis treatment, (2) prostate cancer itself, or (3) patients' co-existing medical conditions, included hot flushes (79%), sleep disturbances (44%), pain (31%),

breast enlargement (30%), breast pain/nipple tenderness (20%), back pain (17%), constipation (15%) and swelling of the extremities (15%).

Pharmacology. The effectiveness of Plenaxis in suppressing serum testosterone was also studied in two randomized, open-label, active-comparator trials. Patients in these trials did not have advanced symptomatic prostate cancer. Patients were randomized such that for every two patients given Plenaxis one patient was given either an LHRH agonist alone or an LHRH agonist plus nonsteroidal antiandrogen. Plenaxis was administered on Days 1, 15, 29, then every 4 weeks thereafter for at least 6 months. LHRH agonist therapy was administered once every 28 days and nonsteroidal antiandrogen therapy was administered daily. After completing 6 months of treatment, patients could continue randomized treatment for an additional 6 months. In both studies combined, 100% (348/348) of Plenaxis patients and 16% (28/172) of comparator patients avoided a testosterone surge. In addition, the percentage of Plenaxis-treated patients who were castrate at Days 2, 4, 8, 15, and 29, was 24%, 56%, 70%, 73% and 94%, respectively.

Additional Safety Information. The description in the following four paragraphs summarizes important safety information contained in the Plenaxis package insert approved by the FDA. Immediate-onset systemic allergic reactions, some resulting in hypotension (lowering of blood pressure) and syncope (fainting), have occurred after administration of Plenaxis. These immediate-onset reactions have been reported to occur following any administration of Plenaxis, including after the initial dose. The cumulative risk of such a reaction increases with the duration of treatment. Following each injection of Plenaxis, patients should be observed for at least 30 minutes in the physician's office and in the event of an allergic reaction, managed appropriately. In all of the prostate cancer clinical trials with Plenaxis (mostly in men without advanced symptomatic disease), immediate-onset systemic allergic reactions occurred in 1.1% (15/1397) of patients treated with Plenaxis. Of the 15 total reactions, seven resulted in hypotension or syncope, representing 0.5% of all patients.

The effectiveness of Plenaxis in suppressing testosterone to castrate levels decreases with continued dosing in some patients. Effectiveness beyond 12 months has not been established. Treatment failure can be detected by measuring testosterone concentrations just prior to administration on Day 29 and every 8 weeks thereafter.

In certain clinical trials comparing Plenaxis to an LHRH agonist alone or an LHRH agonist plus nonsteroidal antiandrogen, clinically meaningful elevations of liver enzymes were observed in both patients who received Plenaxis and those who received the comparator drugs. Liver enzyme levels should be obtained before starting treatment with Plenaxis and periodically during treatment.

In a clinical study comparing Plenaxis to an LHRH agonist plus nonsteroidal antiandrogen, periodic electrocardiograms were performed. Both therapies prolonged the QT interval, which measures a portion of the electrical impulse conduction in the heart, by greater than 10 msec from pre-treatment levels. QTc prolongations can be associated with irregularities of the heart rhythm, which in rare cases, can lead to sudden death. It is unclear whether these changes were directly related to the study drugs, to hormone deprivation therapy or to other variables. Because Plenaxis may prolong the QT interval, physicians should carefully consider whether the risks of Plenaxis outweigh the benefits in patients with elevated QTc levels at the start of treatment and in patients taking certain heart medications.

PLUS Program. As an element of the FDA's approval of Plenaxis, we are marketing Plenaxis under a comprehensive risk management program developed with the FDA to ensure that patients and physicians are fully informed about the risks and benefits of Plenaxis before using it. The PLUS Program includes, among other elements:

- Product labeling regarding the risk of immediate-onset systemic allergic reactions and the decreased effectiveness of Plenaxis in suppressing serum testosterone to castrate levels with continued dosing in some patients;
- An agreement for physicians which must be signed in order to become a prescriber of the drug;

- An agreement for hospital pharmacists confirming their participation in the program and the actions required prior to dispensing the drug;
- A patient information form which patients sign, indicating that they are informed about the risks and benefits of the drug;
- A program for reporting adverse events, including immediate-onset systemic allergic reactions (anaphylaxis, hypotension (lowering of blood pressure) and/or syncope (fainting)) to the Company and the FDA; and
- Measures to actively monitor and evaluate the program, including several phase IV studies.

Product Pipeline

We focus our drug development efforts on conditions or diseases where there are unmet medical needs creating a potential for significant product revenues. In addition to Plenaxis, we have two programs that have moved beyond the research phase into clinical testing, as well as various research and preclinical programs. We continually evaluate in early research potential candidates for development and are currently focusing our discovery efforts on opportunities in the areas of oncology, inflammation and infectious diseases.

We have outlined our clinical programs and our more advanced programs in the research or preclinical development stage, along with the clinical indications they address, in the following table:

Product Candidate	Clinical Indication	Status
Plenaxis (European Union)	Hormonally Responsive Prostate Cancer	MAA Submitted Q2 2003
Plenaxis	Endometriosis	Phase II
Apan	Alzheimer's Disease	Phase I
PPI-2458	Non-Hodgkin's Lymphoma	Phase I-Clinical Hold
PPI-2458	Rheumatoid Arthritis/Cancer	Research/Preclinical
Endometriosis Diagnostic	Endometriosis	Clinical Validation
Androgen Receptor Antagonist	Hormone-Independent Prostate Cancer	Research/Preclinical
Antiviral	Multiple Viruses	Research/Preclinical

Plenaxis Program

Prostate Cancer

European Regulatory Status. In June 2003, we initiated the regulatory submission process in the European Union seeking approval to market Plenaxis for the treatment of a broad population of hormonally responsive prostate cancer patients. We submitted a marketing authorization application, or MAA, in Germany comprised of comprehensive safety and efficacy data from three phase III safety and efficacy studies, one of which was conducted in Europe, one phase III safety study, an open-label study in advanced symptomatic prostate cancer patients, as well as phase I and phase I/II pharmacokinetics studies. We expect the German regulatory authorities to provide initial feedback on our application during the first half of 2004 and to complete its review of the MAA during 2004. Assuming a favorable action by the German regulatory authorities, we plan to seek additional European Union member state approvals under the Mutual Recognition Procedure, or MRP.

We are in discussions with potential partners for the commercialization of Plenaxis in Europe. We are also in discussions regarding the development and/or commercialization of Plenaxis in Japan and other areas of the world. It is likely that the Japanese regulatory authorities would require clinical trials to be conducted in Japanese men prior to a filing for marketing approval in Japan. Other foreign regulatory authorities may also require additional clinical studies. We cannot assure investors that we will be successful in obtaining regulatory approval abroad for the commercialization of Plenaxis for the

treatment of any portion of the hormonally responsive prostate cancer patient population or for any other indication, or that we will be able to enter into collaboration agreements on favorable terms, or at all.

Endometriosis

Background. We have also conducted clinical studies of Plenaxis for the treatment of endometriosis. Endometriosis is a condition where endometrial tissue grows beyond the uterine lining, most often on the surfaces of organs in the pelvic cavity. Endometrial tissue, regardless of location in the body, responds to the normal menstrual cycling of women. When the location of the endometrial tissue prevents the appropriate sloughing of tissue that normally occurs during menstruation, inflammation, gastrointestinal symptoms and internal scarring occur. This causes, among other things, pain, fatigue, heavy menstrual bleeding, painful sexual intercourse and infertility. An estimated 5.5 million females in the United States and Canada suffer from endometriosis. Each year only approximately 300,000 females in the United States are diagnosed with endometriosis, in part due to the lack of a simple diagnostic test. Existing treatments for endometriosis include the use of pain management medications, birth control pills, hormonal therapies to reduce estrogen and surgery.

Endometriosis Clinical Studies. To date, we have completed a 40 patient, phase I/II study and a 363 patient, phase II study. Patients appear to have generally tolerated treatment with Plenaxis well in these studies. As expected, we observed adverse reactions in both Plenaxis and Lupron Depot patients, including headache, temporary and reversible irritation at the injection site and temporary and reversible elevation of some liver enzymes. In addition, it is well documented that the use of hormonal therapies that lower estrogen levels results in bone mineral density loss. Analysis of the results of our phase II study indicates that patients treated with Plenaxis experienced more bone mineral density loss than those treated with the comparator drug, and that this loss was dose-related. In order to better understand the bone mineral density loss, during 2002 and 2003 we conducted a pharmacokinetic study of Plenaxis in healthy women to determine the appropriate dose and dosing schedule necessary to maximize the benefit of the therapy for patients while minimizing attendant bone mineral density loss. The results of this study will be used as guidance for potential future clinical studies. We do not currently have any additional endometriosis studies planned and do not expect to conduct further studies without a corporate partner. Any additional development in endometriosis would also require consultation with the FDA.

Other Potential Indications

Plenaxis, in addition to its approved indication, may have potential use in treating other diseases that respond to the reduction of either testosterone or estrogen. For example, we have completed a small clinical study evaluating the utility of treating hormonally responsive advanced prostate cancer patients with Plenaxis for 12 weeks followed by treatment with LHRH agonist therapy. In addition to our studies in hormonally responsive advanced prostate cancer and endometriosis, a small, investigator-sponsored clinical study was also conducted in which the effects of using Plenaxis to treat androgen-independent prostate cancer were evaluated. In this disease, the prostate cancer cells no longer need testosterone and other hormones to grow and, as a consequence, hormone-lowering therapies are ineffective. The focus of this study was on the suppression of FSH and the results of the study were encouraging. We plan to continue the evaluation of Plenaxis in this patient population through a Company-sponsored study of the use of Plenaxis in patients who have androgen-independent prostate cancer, including those for whom previous hormone therapies have failed, and have submitted a proposed protocol to the FDA for their review.

We are also evaluating the possibility of conducting other small, investigator-sponsored studies in indications where there are unmet medical needs, and where we believe that the benefits of treatment with Plenaxis will outweigh the potential risks. Examples of these diseases may include endometrial cancer, ovarian cancer, breast cancer, benign prostatic hypertrophy and precocious puberty. We intend to work with the FDA to reach agreement on clinical research initiatives, as well as eventual label

expansion, in these and other patient populations which could be appropriately treated with Plenaxis in the future.

Apan

We are developing Apan for the treatment of Alzheimer's disease. Alzheimer's disease affects an estimated 4.5 million people in the United States, and is expected to become increasingly prevalent as the population ages, according to the Alzheimer's Association. Current therapies provide temporary relief for the symptoms of Alzheimer's disease in some patients, but do not affect the progression of the disease itself.

A hallmark of Alzheimer's disease is the accumulation of plaque-like deposits in brain tissue. A major component of this plaque is a small peptide called beta-amyloid. A large body of clinical, biochemical and genetic evidence has emerged suggesting that the aggregation of beta-amyloid peptide may be the underlying cause of Alzheimer's disease. This body of evidence has led to the widely held theory that when single beta-amyloid molecules aggregate they become toxic to nerve cells, and that this toxicity leads to the development and progression of Alzheimer's disease. We used our LEAP technology to select Apan to interfere with this aggregation process.

We have shown in *in vitro* experiments that Apan specifically inhibits the aggregation of beta-amyloid and prevents the associated nerve cell toxicity. In addition, we have shown in rats and mice that Apan reaches the brain in quantities that we believe may be sufficient to block the aggregation of beta-amyloid molecules and alter the course of the disease. Studies in transgenic mice that develop human Alzheimer's disease plaques in their brains and in guinea pigs suggest that Apan can facilitate the clearance of beta-amyloid from the brain. Alzheimer's disease, with the associated accumulation of beta-amyloid in the brain, is often thought of as a defect in the ability to clear excess beta-amyloid from the brain to the cerebrospinal fluid, or CSF. Both humans and transgenic mice with Alzheimer's disease-like plaques show increased levels of beta-amyloid in the brain and decreased levels in the CSF as the disease progresses. In contrast, transgenic mice treated with Apan show increases in beta-amyloid levels in the CSF, suggesting that Apan may be facilitating the clearance of beta-amyloid from the brain.

In March 2003, we completed a phase Ia dose escalation study of Apan in healthy volunteers. In this study, we evaluated the safety and pharmacokinetics of the compound and identified a maximum tolerated dose, or MTD, in healthy volunteers. An analysis of the CSF taken from ten of these healthy volunteers indicates that Apan can be quantified in the CSF. These preliminary CSF results also indicate that Apan may be promoting clearance from the brain of beta-amyloid. This trend in the early data is consistent with the CSF beta-amyloid results we have seen with Apan in animal models.

In June 2003, we initiated a phase Ib trial in Alzheimer's patients. In this study, a single dose of Apan is administered, with the goal of establishing the MTD in patients. We anticipate completing the phase Ib study during the first half of 2004. Upon completion of the phase Ib study, and assuming favorable FDA review of the study's results, we expect to initiate a phase Ic trial examining the safety of multiple administrations of a selected dose of Apan in Alzheimer's disease patients.

PPI-2458

PPI-2458 is a novel, proprietary molecule that acts by irreversibly inhibiting the enzyme methionine aminopeptidase type 2, or MetAP2. PPI-2458 is based on the fumagillin class of compounds. This class of compounds has been shown to prevent both abnormal cell growth and the formation of new blood vessels (known as anti-angiogenesis), which contribute to the growth of aberrant tissues in diseases such as cancer and rheumatoid arthritis. The dose limiting toxicity associated with certain fumagillin derivatives has largely prevented their clinical development. In preclinical studies to date, PPI-2458 has demonstrated the potent activity of this class of compounds while displaying an improved toxicity profile.

In preclinical studies conducted separately by us and the National Cancer Institute, or NCI, using both *in vitro* and animal models, PPI-2458 demonstrated significant anti-tumor activity against certain types of cancerous cell lines. We have also developed a proprietary pharmacodynamic assay that is being utilized in clinical studies to assess the level of inhibition achieved by PPI-2458 of its target enzyme, MetAP2. Data from preclinical studies in the B16F10 xenograft mouse model, which is a commonly used cell line in cancer studies, showed that PPI-2458 significantly inhibited tumor growth and that the degree of growth inhibition was directly linked to the level of MetAP2 inhibition by PPI-2458. The NCI has also presented its data on the anti-angiogenic activity of PPI-2458 and its *in vivo* efficacy in a variety of xenograft animal models of human cancer, which indicate that the activity of PPI-2458 compares favorably to that of another compound of this class known as TNP-470, which was in development at TAP Pharmaceutical Products Inc.

During 2003, we filed an investigational new drug application, or IND, for PPI-2458, and in December 2003, initiated an open-label phase I dose escalation study in non-Hodgkin's lymphoma patients. In March 2004, the FDA placed this trial on clinical hold until questions relating to a finding in a recently completed animal safety study have been satisfactorily resolved. In support of our IND, we had completed and submitted to the FDA results from preclinical studies evaluating the safety of PPI-2458 through 28-days of treatment. These studies showed no evidence of any unexpected safety issues. The FDA's decision was related to a preliminary finding in a recently completed three-month animal safety study. The results of this study were not available at the time that the clinical study was initiated. The finding consisted of a neuropathological abnormality in some of the animals tested, similar to findings reported in connection with certain other approved products. The FDA has confirmed in writing that we will need to submit a detailed plan in order to address this finding. We intend to further explore this finding, with input from leading experts as appropriate, to assess its potential implications and prepare a plan for the FDA. While we intend to work diligently with the FDA to resolve this issue, we cannot currently predict when the clinical hold will be released.

Assuming that the FDA releases the clinical hold, we will resume our phase I clinical study of PPI-2458 in non-Hodgkin's lymphoma patients. The primary endpoint of this study is safety, with disease response being evaluated as a secondary endpoint. In this study, we are utilizing our MetAP2 inhibition assay to assist in the determination of a safe and efficacious dosing regimen for future studies. Initial results collected prior to the clinical hold confirm that orally dosed PPI-2458 is achieving inhibition of its molecular target, MetAP2, in humans.

There are approximately 50,000 new cases of non-Hodgkin's lymphoma in the United States annually, and approximately 25,000 deaths from non-Hodgkin's lymphoma each year. The PPI-2458 trial includes patients with diffuse large B-cell lymphoma and follicular lymphoma. These two types of non-Hodgkin's lymphoma represent approximately one half of all newly diagnosed non-Hodgkin's lymphoma cases in the United States.

In December 2003, we entered into a collaboration with the NCI's Division of Cancer Treatment and Diagnosis for the expansion of clinical development of PPI-2458 for the treatment of various forms of cancer. Under the collaboration agreement, we will work with the NCI to optimize a clinical development path for PPI-2458 in cancers other than non-Hodgkin's lymphoma. However, the Division of Cancer Treatment and Diagnosis can not proceed with the initiation of any clinical trials under this agreement until release of the recently imposed clinical hold discussed above.

- We intend to continue to evaluate potential trials for PPI-2458 in autoimmune diseases, including rheumatoid arthritis. Preclinical studies have demonstrated the efficacy of PPI-2458 in several rodent models of rheumatoid arthritis, including a rodent model of collagen-induced arthritis. In one such study, radiographs showed that, as compared to the untreated control group, PPI-2458 significantly inhibited structural damage when the compound was administered via any of three routes: oral, subcutaneous or intravenous. Despite the availability of several new effective disease-modifying anti-rheumatic drugs, also known as DMARDs, for the treatment of rheumatoid arthritis, there remains a significant unmet medical need. We believe that new drugs which could be used alone or in combination with established DMARDs could be useful in treating rheumatoid arthritis.

Endometriosis Diagnostic

Considering that an estimated 5.5 million females in the United States and Canada suffer from endometriosis, and that only approximately 300,000 females in the United States and an unknown number in Canada are actually diagnosed with the disease annually, we believe a diagnostic test is critical to better identify, assess and treat those who suffer from the disease. Currently, endometriosis is diagnosed by a relatively painful and expensive invasive surgical procedure called laparoscopy. We are developing a simple, non-invasive endometriosis diagnostic test based on the presence of unique proteins in the serum of disease sufferers. Using our Biomarker Discovery Platform described below, we have discovered proteins whose abundance in serum can discriminate between diseased and non-diseased individuals. These proteins could prove useful to diagnose individuals with the disease, as well as enhance understanding of the disease process. We have developed a clinically relevant diagnostic test which can be performed on a commercially available platform. This will allow for the implementation and further clinical assessment of our findings in a broad population. If the findings hold, we believe that this test could be available in a specialty testing laboratory environment on an expedited timetable.

Androgen Receptor Antagonist

Because testosterone and other hormones are growth factors for prostate cancer cells, hormone-lowering therapy can be a safe and effective treatment for patients with hormone-dependent prostate cancer. However, most patients eventually progress to a condition known as hormone-independent (or androgen-independent) prostate cancer, where the prostate cancer cells no longer need testosterone and other hormones to grow and, as a consequence, hormone-lowering therapies are ineffective. Genetic studies in these patients reveal that many of them have accumulated mutations in the gene encoding the Androgen Receptor, or AR, allowing it to function in the absence of testosterone. These studies indicate that the AR is central to the growth of prostate cancer cells. In an ongoing effort to develop the most advanced approaches to treating prostate cancer, we have discovered and are testing ligands that bind to the AR using our LEAP technology, which could provide the basis for a new class of drugs to treat hormone-independent prostate cancer. If successful, the use of these drugs could be expanded to treat prostate cancer at all stages.

Antiviral Program

The development of antiviral agents has captured a worldwide market in excess of $9.0 billion. Most antiviral therapeutics directly interfere with components of viral entry, replication or assembly. However, this therapeutic approach often leads to resistance, as the virus mutates, overcomes the action of the drug and successfully enters the target cell nucleus.

We have been working across a number of different approaches in pursuit of potential antiviral therapies. For example, we are pursuing a novel strategy targeting cellular pathways which would prevent/reduce viral replication and thereby potentially avoid the problems of drug resistance. Using our LEAP technology, we have identified molecules that cause an antiviral effect; preventing the viral replication, against several different classes of viruses. We are currently testing the activity of these compounds against a wider spectrum of viruses, and are working on improving the potency of these molecules through the medicinal chemistry step of the LEAP process. If we are successful, the use of these molecules could be developed for the treatment of a number of different viral afflictions, such as influenza and respiratory syncytial virus, or RSV.

Technology

LEAP and Direct Select

Our proprietary method for discovering drugs is based on a unique system that combines the power and diversity of biological selection to identify compounds with potentially favorable drug-like properties with an ability to enhance and optimize these compounds using medicinal chemistry. We call this process Ligand Evolution to Active Pharmaceuticals, or LEAP. We believe LEAP is superior to traditional methods of drug discovery that are limited by the number of compounds that can be synthesized and tested manually. In a typical LEAP selection process, we can examine millions of molecules in a few months. By contrast, conventional screening and medicinal chemistry permit the examination of fewer than one million molecules with equivalent resources and require more time.

In the case of Plenaxis, LEAP allowed us to take a peptide ligand encoded in the human genome and convert that peptide into a drug. GnRH is a natural peptide ligand that binds to the GnRH receptor on the pituitary gland triggering the production of LH, which, in turn, triggers the production of testosterone. We used LEAP to evolve GnRH into Plenaxis, a drug that binds to the same receptor target, but blocks the production of LH. We have several granted foreign patents, as well as pending patent applications in the United States and abroad, that cover the essential steps of the LEAP process.

As part of the ongoing evolution of our discovery platform, we have recently developed Direct Select Technology. The power of the Direct Select Technology is in both the sheer size of the small molecule libraries—10,000 times the size of compound libraries typically used in the pharmaceutical industry—and the ease of use of the libraries in affinity-based screening assays. Direct Select libraries are not restricted to peptide-based compounds and accomplish what takes two steps in LEAP in a single step selection. Due to these advantages, Direct Select Technology will allow us to rapidly and directly identify leads with higher affinity and specificity than is routinely possible using traditional drug discovery methods. In a pilot trial using Direct Select Technology, we generated a 250,000 member library in less than six weeks. Our scientists are scaling the process to potentially create multiple libraries consisting of greater than 100 million molecules with highly diverse structures. We intend to apply the Direct Select approach to the discovery of new compounds, including orally bioavailable drugs, directed at multiple targets in select human diseases. We have filed patent applications in the United States covering the essential steps of the Direct Select process and also intend to pursue patent protection abroad.

Rel-Ease

We may be able to further enhance the potential clinical utility of our drug candidates by formulating the drugs with our proprietary sustained release technology, Rel-Ease. For example, using Rel-Ease technology, we are able to formulate Plenaxis in such a way that a physician only needs to administer it to prostate cancer patients once every four weeks because Rel-Ease continuously releases the drug in the body over that period of time. In many cases, infrequent injections of a drug in a sustained release formulation are more desirable than oral administration due to patient compliance, convenience or reimbursement issues. We have formulated a variety of molecules with Rel-Ease technology and believe that Rel-Ease may be useful for formulating drug candidates we discover and develop using our proprietary technology platforms. We may explore in the future the potential use of our Rel-Ease technology to create improved formulations and sustained release formulations of approved drugs. We hold patents that cover the general application of this technology for a broad range of peptide-based drugs.

Biomarker Discovery Platform

Our LEAP technology platform includes a process to profile highly complex tissues and recognize subtle differences between them. The recognition of differences in complex tissues is a core challenge of performing global protein profiling, or proteomics, to look for diagnostic biomarkers or novel insight

into disease mechanisms which could lead to new drug targets and therapies. This technology platform uses liquid chromatography and mass spectrometry to reproducibly measure the relative abundance of many components in tissue samples. Proprietary software is used to distinguish between normal subjects and disease sufferers. The structures of the molecules having different abundances are then determined. As discussed above, we recently employed this proteomics-based Biomarker Discovery Platform successfully in our endometriosis diagnostic program to identify the presence of unique proteins in the serum of disease sufferers.

MASTRscreen

MASTRscreen is our proprietary screening procedure that rapidly identifies and evaluates ligands for the most successful class of drug targets, known as G-protein coupled receptors. The GnRH receptor is a member of this class of receptors. We developed MASTRscreen in connection with our Plenaxis program, and it was instrumental in the selection of Plenaxis from pools of modified peptides. MASTRscreen is useful because of its sensitivity to low concentrations of screened material, easily measurable endpoints and adaptability to various screening systems. We have several granted foreign patents, as well as pending patent applications in the United States and abroad, that cover the essential steps of the MASTRscreen process.

Technology License

In October 1996, we entered into a license agreement with Indiana University Foundation. The license agreement was amended in June 1998, and Indiana University Foundation assigned it to Indiana University's Advanced Research and Technology Institute, Inc. Under the agreement, we have an exclusive worldwide license under patent applications, future patents and technology of Indiana University Foundation relating to GnRH antagonist compounds, including abarelix, which is the active ingredient of Plenaxis, and methods of use for abarelix. Through December 31, 2003, we had paid non-refundable fees of $305,000 and performance-based payments of $1.75 million under this agreement. We made an additional $1.0 million performance-based payment under this agreement in February 2004. We have agreed to make performance-based payments of up to an additional $1.5 million, and to pay royalties on our net sales of products covered by the license. The license agreement remains in effect until the last licensed patent expires, currently 2015. Expiration of the license will not preclude us from continuing to develop and market the licensed products and use the licensed technology, provided we obtain the consent of Advanced Research and Technology Institute to extend the license term past the expiration date. Advanced Research and Technology Institute may not unreasonably withhold its consent to our request for such an extension. We can terminate the agreement at any time upon 90 days notice. Advanced Research and Technology Institute may terminate upon 90 days notice if we materially breach the agreement or fail to make required payments.

Research and Development

As of December 31, 2003, we had a total of 99 employees dedicated to research and development for our product candidates. We have spent substantial funds over the past three years to develop Plenaxis and our other potential drug candidates and expect to continue to do so in the future. We spent approximately $59.4 million in 2001, $56.4 million in 2002 and $41.9 million in 2003 on research and development activities.

Marketing and Sales

We have established an internal marketing and sales infrastructure to support the launch of Plenaxis in the United States, including marketing and sales support professionals based at our headquarters in Waltham, Massachusetts. As of February 29, 2004, we have hired and trained our regional sales managers and are aggressively hiring and training what we currently estimate will be 40 field sales representatives. In addition to marketing and sales personnel, we have hired and trained

medical science liaisons to engage in scientific exchange and help respond to medical and scientific questions from physicians.

Our goal is to have 100% of our Plenaxis sales force hired, trained and in the field by early in the second quarter of 2004. We are targeting sales representatives with an average of 6-8 years of experience. Our sales force will promote Plenaxis to physicians, particularly oncologists and urologists, who are involved in the treatment of patients with advanced symptomatic prostate cancer, as well as educate physicians and hospital pharmacists about the PLUS Program and the risks and benefits of Plenaxis.

We intend to leverage our marketing and sales infrastructure to position ourselves as a partner for commercializing other urology/oncology products. In addition, our marketing professionals are also involved with our product candidates at earlier stages of development, such as Apan and PPI-2458. As these products advance in development, our commitment of marketing resources may increase.

We sell Plenaxis directly to authorized specialty distributors who, in turn, sell the product to physicians and hospital pharmacists enrolled in the PLUS Program. There are a relatively small number of specialty distributors and wholesalers that provide such services. There can be no assurances that these distributors will adequately provide their services to either end users or to the Company.

Manufacturing

We generally manufacture in-house the drug supply required to support our early preclinical studies. External contractors provide all of our later-stage preclinical and clinical supplies and manufacture them in accordance with FDA and European regulations. We have long-term contracts for each stage of the commercial manufacturing process for Plenaxis.

We have a development and supply agreement with UCB S.A. under which UCB will supply us with commercial volumes of the Plenaxis drug compound. We have no minimum purchase commitment for commercial supply under the UCB agreement.

We also have a supply agreement with Cambrex Charles City, Inc., formerly Salsbury Chemicals, Inc. Under this supply agreement, Cambrex has agreed to manufacture for us the commercial depot formulations of Plenaxis. We contributed approximately $6.0 million toward Cambrex's construction and outfitting of a dedicated manufacturing facility. We retain all rights in manufacturing technology developed in connection with this agreement. During 2003, we paid Cambrex approximately $632,000 toward minimum purchase commitments and facility maintenance. Our minimum purchase commitment with Cambrex for 2004 is $792,000.

In addition, we have a commercial supply agreement with Baxter Pharmaceutical Solutions LLC to supply Plenaxis products in finished vials. Under the terms of the Baxter agreement, we are required to purchase a minimum of $375,000 of product from Baxter each calendar year until January 2005, the first anniversary of the first commercial shipment of Plenaxis, at which time the minimum annual purchase commitment will be adjusted to $650,000.

In order to meet potential increases in demand in connection with the commercial launch of Plenaxis, we are evaluating the possibility of a second source for certain stages of Plenaxis production. However, the number of qualified alternative suppliers is limited, and we cannot assure investors that we will be able to locate alternative suppliers or negotiate second supply agreements on reasonable terms. Furthermore, the process of engineering a new supplier's facility for the production of Plenaxis and obtaining the necessary FDA approval of the facility would require substantial lead-time and could be extremely costly. We cannot assure investors that we will not lose one or more of our suppliers, or that in such event we would be readily able to continue the commercialization and sale of Plenaxis products or the further development of Plenaxis without substantial and costly delays.

Patents and Proprietary Rights

Proprietary protection for our products, technology and processes is essential to our business. We seek proprietary protection predominantly in the form of patents on our products and the processes we use to discover them. With respect to a particular product, we generally seek patent protection on the compound itself, its commercial formulation, its range of applications and its production. Where possible, we also seek patent coverage that could prevent the marketing of, or restrict the commercial threat of, competitive products.

We currently hold 24 United States patents and exclusive licenses to three United States patents. These patents have expiration dates from 2012 through 2020. We also hold or have exclusive licenses to 65 granted foreign patents. In addition, we have filed or hold exclusive licenses to 33 United States utility and provisional patent applications, as well as 131 related foreign patent applications, including both Patent Cooperation Treaty filings and national filings. We also have non-exclusive licenses to four United States patents directed to technologies embodied in LEAP.

In particular, we have or hold exclusive licenses to United States patents that cover both the active ingredient of Plenaxis, known as abarelix, as well as methods of use for abarelix for treating a variety of conditions, including prostate cancer, and the sustained release formulation enabling its once-per-month administration. These patents expire in 2015 and 2016. We also have patents covering the use of abarelix and certain specific uses of any other GnRH antagonist in various therapeutic settings, including in combination with surgery or radiation therapy. We intend to file additional United States and foreign patent applications, where appropriate, relating to new product discoveries or improvements.

We also rely on trade secrets, know-how and continuing technological advances to protect various aspects of our core technology. We require our employees, consultants and scientific collaborators to execute confidentiality and invention assignment agreements with us to maintain the confidentiality of our trade secrets and proprietary information. These agreements generally provide that the employee, consultant or scientific collaborator will not disclose our confidential information to third parties, compete with us or solicit our employees during the course of their employment, consultancy or collaboration with us. When appropriate, these agreements also provide that inventions conceived by the employee, consultant or scientific collaborator in the course of working for us will be our exclusive property. Additionally, our employees agree, for one year following termination of their employment with us, not to solicit our other employees.

Competition

A biopharmaceutical company such as ours faces intense competition. Many companies, both public and private, including large pharmaceutical companies, chemical companies and biotechnology companies, develop products or technologies competitive with our products or technologies. Many of these companies have greater financial resources and more experience than we do in developing drugs, obtaining regulatory approvals, manufacturing and marketing. In addition, academic, government and industry-based research is intense, resulting in considerable competition in obtaining qualified research personnel, submitting patent filings for protection of intellectual property rights and establishing strategic corporate alliances.

Our product, Plenaxis, as well as each of our potential products in research or development, will face competition from other products. For example, Plenaxis, although approved in the United States only for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration, will still compete to some extent with established or newly introduced products, including Lupron Depot, Zoladex, Casodex and other pharmaceuticals used by physicians for the treatment of hormonally responsive advanced prostate cancer in the United States and Europe.

We are also aware of another GnRH antagonist, Degarelix, being developed by Ferring Pharmaceuticals, which is in late-stage clinical trials for the treatment of prostate cancer. In addition, for Plenaxis and each of our product candidates, we will face increasing competition from generic formulations of existing drugs whose active components are no longer covered by patents. Specifically, we are aware of various formulations of leuprorelin, the active ingredient of Lupron Depot, including Viadur™, marketed by Bayer Corporation as a 12-month hormone therapy implant, and Eligard, marketed by Atrix Laboratories, Inc. in one-, three- and four-month depot formulations for the treatment of advanced prostate cancer.

We believe that the principal competitive factors affecting the market for Plenaxis are the safety and efficacy profile, physician and patient acceptance of the product, product features, including the dosing schedule, and pricing and reimbursement decisions. We believe that Plenaxis will be adopted by practitioners and patients as an acceptable therapy for the subset of advanced symptomatic prostate cancer patients described above and will compete favorably with other available treatment alternatives in this arena, although no assurance can be given in this regard.

Government Regulation

The manufacture and marketing of pharmaceutical products and our ongoing research and development activities in the United States require the approval of numerous governmental authorities, including the FDA. We also must obtain similar approvals from comparable agencies in most foreign countries. The FDA has established mandatory procedures and safety standards which apply to preclinical testing and clinical trials, as well as to the manufacture, storage, distribution, marketing, sales, import and export of pharmaceutical products. State, local and other authorities also regulate pharmaceutical manufacturing and distribution facilities.

The pharmaceutical research, development and approval process in the United States is typically intensive, uncertain, lengthy and rigorous and can take many years, depending on the product under consideration. As an initial step in the FDA regulatory approval process, an applicant typically conducts preclinical studies in animals to assess a drug's efficacy and to identify potential safety problems. An applicant must conduct specified preclinical laboratory and animal studies in compliance with the FDA's good laboratory practice regulations. Failure to follow these requirements can invalidate the data, among other things. An applicant must submit the results of these studies to the FDA as part of an investigational new drug application, or IND. Proposed clinical testing can only begin if the FDA raises no objections to the IND. We can give no assurance that any submission of an IND to the FDA relating to our product candidates will result in the commencement of a clinical trial. The FDA may prevent studies from moving forward by imposing a clinical hold, and may suspend or terminate studies once initiated. For example, the FDA recently placed our phase I clinical trial of PPI-2458 on hold due to a neuropathological abnormality observed in some of the animals tested in a recently completed three-month animal safety study. The FDA has confirmed in writing that we will need to submit a detailed plan to address this finding. We intend to further explore this finding, with input from leading experts as appropriate, to assess its potential implications and prepare a plan for the FDA. While we intend to work diligently with the FDA to resolve this issue, we cannot currently predict when the clinical hold will be released.

Clinical testing must meet requirements for institutional review board, or IRB, oversight and study subject informed consent, as well as FDA prior review, oversight and good clinical practice requirements. Independent IRB's are responsible for overseeing studies at particular sites and protecting human research study subjects. An IRB may prevent a study from beginning or suspend or terminate a study once initiated. Typically, clinical testing involves a three-phase process. Phase I clinical trials involve a small number of subjects and are designed to provide information about both product safety and the expected dose of the drug. Phase II clinical trials generally provide additional information on dosing and safety in a limited patient population. Generally, phase II trials may also provide preliminary evidence of product efficacy. Phase III clinical trials are large-scale, well-controlled studies. The goal of phase III clinical trials generally is to provide statistically valid proof of efficacy, as

well as safety, in the target patient population. In order to seek approval to commence commercial sales, the company performing the preclinical testing and clinical trials of a pharmaceutical product then submits the results to the FDA in the form of a new drug application, or NDA, along with proposed labeling for the product and information about the manufacturing processes and facilities that will be used to ensure product quality. Each NDA submission requires a substantial user fee payment for which the FDA has committed generally to review and make a decision concerning approval within 10 months, and of a new "priority" drug within 6 months. However final FDA action on the NDA can take substantially longer and also may involve review and recommendations by an independent FDA advisory committee. Preparing NDA applications involves considerable data collection, verification, analysis and expense. In responding to an NDA, the FDA may conduct a pre-approval inspection of the relevant manufacturing facility or facilities to assess conformance to the current good manufacturing practice requirements and may also inspect sites of clinical investigators involved in the clinical development program to ensure their conformance to good clinical practices.

The FDA must grant approval of our products, which includes a review of the manufacturing processes and facilities used to produce these products, before we can market these products in the United States. The process of obtaining approvals from the FDA can be costly, time consuming and subject to unanticipated delays. The FDA may not approve an NDA, or may require revisions to the product labeling, require that additional studies be conducted prior to or as a condition of approval, or impose other limitations or conditions on product distribution, including, for example, adoption of a special risk management plan. If the FDA grants approval of a drug product, the approval will be limited to specific indications.

The FDA has considerable discretion in determining whether to grant marketing approval for a drug, and may delay or deny approval even in circumstances where the applicant's clinical trials have proceeded in compliance with FDA procedures and regulations and have met the established end-points of the trials. Challenges to FDA determinations are generally time-consuming and costly, and rarely if ever succeed. In November 2003, we received FDA approval to market Plenaxis for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration. We can give no assurance that we will obtain marketing approval for any of our other product candidates.

Now that we have received marketing approval for Plenaxis, we must comply with FDA requirements for manufacturing, labeling, advertising, record keeping and reporting of adverse experiences and other information. In addition, we must seek FDA approval for any significant changes to the product, the manufacturing of the product, or the labeling. Drug advertising and promotion are subject to federal and state regulations. In the United States, the FDA regulates all company and product promotion, including direct-to-consumer advertising. Violative materials may lead to FDA enforcement action. The manufacturing of a product after approval is also subject to comprehensive and continuing regulation. These regulations require the manufacture of products in specific approved facilities and in accordance with current good manufacturing practices, and to list products and register manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. All manufacturing facilities are subject to comprehensive, periodic inspections by the FDA.

In addition, Plenaxis has been approved under regulations concerning drugs with certain safety profiles, under which the FDA has established special restrictions to ensure safe use. Under these regulations, Plenaxis was approved with a comprehensive risk management program. This program includes educational outreach to patients and physicians regarding the risks and benefits of Plenaxis, restricted distribution of the product only to physicians enrolled in a prescribing registry, a system for collecting and reporting adverse events to the FDA and auditing requirements to evaluate the effectiveness of the program. We are also required to conduct several phase IV studies to evaluate the risk management program and the appropriate use of the drug in the indicated population. These regulations also give the FDA authority to pre-approve all promotional materials and permit an expedited market withdrawal procedure if issues arise regarding the safe use of Plenaxis.

Our manufacturing, sales, promotion, and other activities following product approval are subject to regulation by numerous regulatory authorities in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, and state and local governments. Any distribution of pharmaceutical samples to physicians must comply with applicable rules, including the Prescription Drug Marketing Act. Our sales, marketing and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the False Claims Act, and similar state laws. Our pricing and rebate programs must comply with pricing and reimbursement rules, including the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead FDA to modify or withdraw a product approval.

We also are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure you that accidental contamination or injury from these materials will not occur. Compliance with laws and regulations relating to the protection of the environment has not had a material effect on our capital expenditures or our competitive position. However, we cannot accurately predict the extent of government regulation, and the cost and effect thereof on our competitive position, which might result from any legislative or administrative action.

Additionally, we will likely need to obtain approval of a product from comparable regulatory authorities in foreign countries prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, may involve additional testing and the time required may differ from that required for FDA approval. Under the current regulatory system in the European Union, marketing authorization applications may be submitted pursuant to a centralized, a decentralized or a national level process. The centralized procedure is mandatory for the approval of biotechnology products and high technology products and available at the applicant's option for other products. The centralized procedure provides for the grant of a single marketing authorization that is valid in all European Union member states. The decentralized procedure is available for all medicinal products that are not subject to the centralized procedure. The decentralized procedure provides for mutual recognition of national approval decisions, changes existing procedures for national approvals and establishes procedures for coordinated European Union actions on products, suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more European Union member states, certify that the dossier is identical to that on which the first approval was based or explain any differences and certify that identical dossiers are being submitted to all member states for which recognition is sought. Within 90 days of receiving the application and assessment report, each European Union member state must decide whether to recognize approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. Lack of objection of a given country within 90 days automatically results in approval of the European Union country. Following receipt of marketing authorization in a member state, we would then be required to

engage in pricing discussions and negotiations with a separate prescription pricing authority in that country.

We intend to secure European regulatory approval for the use of Plenaxis for hormonally responsive prostate cancer under the decentralized procedure and filed our first MAA in Germany in June 2003. That review is currently pending. We are relying primarily on third party contractors to assist us with our European regulatory filings for Plenaxis. However, although we have sought qualified experience and assistance in dealing with the foreign regulatory processes and interacting with foreign regulatory authorities, we cannot assure investors that we will be successful in filing for and obtaining the necessary governmental approvals for Plenaxis or any of our other product candidates in Europe or any other foreign country.

Price Controls

In many of the markets where we operate or intend to operate, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

In the United States, debate over the reform of the health care system has resulted in an increased focus on pricing. Although there are currently no government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs. Various states have adopted mechanisms under Medicaid and otherwise that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. In the absence of new government regulation, managed care has become a potent force in the marketplace that increases downward pressure on the prices of pharmaceutical products. New federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs covered by Medicare are reimbursed, generally leading to lower reimbursement levels. The legislation has also added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. While these negotiations may increase pricing pressures, it is also possible that the new Medicare prescription drug benefit may increase the volume of pharmaceutical drug purchases, offsetting, at least in part, potential price discounts. The new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, but some members of Congress are still pursuing legislation that would permit the United States government to use its enormous purchasing power to demand discounts from pharmaceutical companies thereby creating de facto price controls on prescription drugs.

This focus on pricing has led to other adverse government action, and may lead to other action in the future. For example, in December 2003 federal legislation was enacted to change United States import laws and expand the ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time. However, it is possible that this Secretary or a subsequent Secretary could make the certification in the future. In addition, legislative proposals have been made to implement the changes to the import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may increase due to market and political forces, and the limited enforcement resources of the FDA, the Customs Service, and other government agencies. For example, numerous states and localities have proposed programs to facilitate Canadian imports, and at least one

locality has already begun such a program, notwithstanding questions raised by FDA about the legality of such actions. We expect that pressures on pricing and operating results will continue.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the United Kingdom which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

In Japan, the National Health Ministry biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions.

Product Liability Insurance

We maintain product liability insurance for the manufacturing and commercial sale of Plenaxis, as well as for clinical trials, in the amount of $20.0 million per occurrence and $20.0 million in the aggregate. Although we maintain product liability insurance, we cannot be sure that this coverage is adequate or that it will continue to be available to us on acceptable terms. Insurance coverage is becoming increasingly expensive, and we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We may incur significant liability and our business would be harmed if product liability or malpractice lawsuits against us are successful. Furthermore, product liability claims, regardless of their merits, could be costly and divert management's attention from other business concerns, or adversely affect our reputation and the demand for Plenaxis.

Human Resources

As of February 29, 2004, we had 175 full-time employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and potential commercialization of our products. None of our employees are party to a collective bargaining agreement and we have never experienced a work stoppage. We consider our employee relations to be good. We believe that our future success is dependent in part on our ability to attract and retain skilled scientific, sales and marketing, and other professional and senior management personnel. Competition in our industry is intense and we cannot assure you that we will be able to attract, integrate and retain these personnel.

Available Information

We maintain a website with the address www.praecis.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission. We have adopted a code of ethics that applies to all of our directors, officers and employees. We have made a copy of our code of ethics available on our website under "Investor Relations—Corporate Governance." We may satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or a waiver from, a provision of our code of ethics that applies to our principal executive officer or our principal financial and accounting officer by posting such information on our website.

ITEM 2. PROPERTIES.

Our corporate headquarters and principal research facility is located in Waltham, Massachusetts, where we own, through our wholly owned real estate subsidiary, land and a building of approximately 175,000 square feet. We have entered into a 15-year lease for this facility with our subsidiary. We currently occupy approximately 100,000 square feet of this facility and would sublease a portion of the remaining space for up to the next three to five years upon acceptable financial terms. In connection with the acquisition of our corporate headquarters and principal research facility, our subsidiary granted a security interest in the facility, together with all fixtures, equipment, improvements and related items, as more fully discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" appearing elsewhere in this report.

We believe that our facility will be adequate for at least the next seven years and that we will be able to obtain additional space as needed on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS.

We are not currently a party to any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders of the Company during the last quarter of the fiscal year ended December 31, 2003.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on The Nasdaq National Market under the symbol "PRCS." The following table shows the range of high and low per share sale prices of our common stock as reported on The Nasdaq National Market for the periods indicated.

	Common Stock Price	
	High	Low
Year Ended December 31, 2003:		
First Quarter	$4.49	$2.90
Second Quarter	5.80	3.83
Third Quarter	7.25	4.51
Fourth Quarter	7.98	6.25
Year Ended December 31, 2002:		
First Quarter	$5.94	$4.24
Second Quarter	5.80	2.71
Third Quarter	3.93	2.60
Fourth Quarter	3.54	2.20

As of February 29, 2004, there were approximately 143 holders of record of our common stock registered with our transfer agent, American Stock Transfer & Trust Company. Because many of these shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by the record holders.

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Our board of directors will determine future dividends, if any, based upon our financial condition, results of operations, capital requirements and other factors that the board deems relevant. Therefore, you should not expect to receive any funds in respect of shares of our common stock without selling your shares.

The information under the heading "Equity Compensation Plan Information" in the Company's definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004 is incorporated into Item 12 of this report by reference.

ITEM 6. SELECTED FINANCIAL DATA.

You should read the following selected financial data in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this report. We have derived our statement of operations data for each of the three years in the period ended December 31, 2003, and our balance sheet data at December 31, 2002 and 2003, from our financial statements that have been audited by Ernst & Young LLP, independent auditors, and which we include elsewhere in this report. We have derived the statement of operations data for the years ended December 31, 1999 and 2000 and the balance sheet data at December 31, 1999, 2000 and 2001 from our audited financial statements, which we do not include in this report.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Corporate collaboration revenue	$ 61,514	$ 61,189	$ 9,907	$ 1,029	$ —
Costs and expenses:					
Research and development	48,764	85,915	59,416	56,383	41,907
Sales and marketing	2,601	6,444	8,737	1,837	5,234
General and administrative	3,572	5,285	6,961	9,676	10,006
Total costs and expenses	54,937	97,644	75,114	67,896	57,147
Operating income (loss)	6,577	(36,455)	(65,207)	(66,867)	(57,147)
Gain on assignment of leasehold improvements	—	—	1,499	—	—
Gain on termination of collaboration agreement	—	—	—	16,020	—
Interest income, net	4,473	7,819	9,105	4,772	1,349
Income (loss) before income taxes	11,050	(28,636)	(54,603)	(46,075)	(55,798)
Provision for income taxes	1,800	100	—	—	—
Net income (loss)	$ 9,250	$ (28,736)	$ (54,603)	$ (46,075)	$ (55,798)
Net income (loss) per share:					
Basic	$ 1.51	$ (0.95)	$ (1.10)	$ (0.89)	$ (1.08)
Diluted	$ 0.24	$ (0.95)	$ (1.10)	$ (0.89)	$ (1.08)
Weighted average number of common shares:					
Basic	6,106	30,259	49,777	51,678	51,869
Diluted	37,849	30,259	49,777	51,678	51,869

	December 31,				
	1999	2000	2001	2002	2003
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 94,525	$ 132,207	$ 266,216	$ 195,035	$ 143,192
Working capital	86,220	115,733	229,028	185,523	132,981
Total assets	140,331	195,571	342,125	268,250	212,478
Long-term debt (including current portion)	—	24,000	33,000	33,000	32,627
Total stockholders' equity	87,716	146,531	270,696	224,890	169,661

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

General

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and notes thereto appearing elsewhere in this report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ substantially from those anticipated in these forward-looking statements.

Overview

Since our inception, we have been engaged in developing drugs for the treatment of a variety of human diseases. Our lead program is the development of Plenaxis (abarelix for injectable suspension), a drug for the treatment of diseases that respond to the lowering of certain hormone levels. In November 2003, the FDA approved Plenaxis for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration. For safety reasons, Plenaxis was approved with marketing restrictions. Only physicians enrolled in the PLUS (PLenaxis User Safety) Program may prescribe Plenaxis. We are promoting Plenaxis in the United States through our own dedicated marketing and sales team.

In June 2003, we initiated the regulatory submission process in the European Union seeking approval to market Plenaxis for the treatment of a broad population of hormonally responsive prostate cancer patients. We submitted a marketing authorization application, or MAA, in Germany and, assuming a favorable action in Germany, plan to seek additional European Union member state approvals under the Mutual Recognition Procedure, or MRP. We believe that the German review process will be completed during 2004. We are in discussions with potential partners for the commercialization of Plenaxis in Europe, as well as for the development and/or commercialization of Plenaxis in Japan and other areas of the world.

We are conducting clinical trials of Apan, our proprietary drug candidate for the treatment of Alzheimer's disease. PPI-2458 is our proprietary compound in development for the potential treatment of a wide range of cancers, as well as certain autoimmune diseases. During the fourth quarter of 2003, we initiated a phase I clinical trial to study PPI-2458 in patients with non-Hodgkin's lymphoma. In March 2004, the FDA placed this trial on clinical hold. We also have other programs in the research or preclinical development stage.

Since our inception, we have had no revenues from product sales. Substantially all of our expenditures to date have been for drug development and commercialization activities and for general and administrative expenses. In the past, a significant portion of our revenues was received under collaboration agreements through which we converted the potential value underlying our Plenaxis program into a stream of upfront, milestone and expense reimbursement payments from corporate collaborators. In 2001, we regained full ownership of our Plenaxis program and, as a result, all revenues and ongoing financial obligations under our former collaboration agreements have ended. We had entered into collaborations with Amgen and Sanofi-Synthélabo to develop and commercialize our Plenaxis products. In September 2001, Amgen notified us that it was terminating its agreement with us. In October 2001, Sanofi-Synthélabo notified us that it was terminating its agreement with us. Both terminations were effective in December 2001. As a result, all of the licenses for Plenaxis granted to Amgen and Sanofi-Synthélabo under these agreements, and all rights of Amgen and Sanofi-Synthélabo in the Plenaxis program, have terminated. In 2002, we entered into an agreement relating to the termination of these collaborations with each of Amgen and Sanofi-Synthélabo.

Due primarily to the costs associated with the commercialization of Plenaxis in the United States, as well as other research and development and general and administrative expenses, and our lack of revenues, we had a net operating loss during 2003. Our accumulated deficit as of December 31, 2003 was approximately $186.3 million. We expect to continue to have net operating losses through 2005. We began selling Plenaxis in the United States in January 2004. Assuming the successful commercialization

of Plenaxis, partnering of clinical programs at opportune times and continued prudent fiscal management, we believe that our existing cash and investments will be sufficient for us to execute our current operating plan and attain profitability by 2006.

The market for currently available hormonal therapies to treat prostate cancer is approximately $1.2 billion in the United States. We believe that the revenue opportunity for Plenaxis, based upon its approved indication, may represent 15% or more of this market. However, our actual revenues will depend upon the impact of our risk management program, physician and patient acceptance of Plenaxis and the overall success of our commercialization efforts.

At December 31, 2003, we had 146 full-time employees, 99 of whom were engaged in research and development activities, compared to 139 full-time employees at December 31, 2002, 110 of whom were engaged in research and development activities.

The termination of our collaboration agreement with Sanofi-Synthélabo became effective as of December 31, 2001 and we received a final reimbursement payment of approximately $1.0 million during the second quarter of 2002. Including this payment, we recognized a total of approximately $24.7 million in non-refundable fees and performance-based payments, and a total of approximately $11.7 million in reimbursement for ongoing development costs under this agreement.

The termination of our collaboration agreement with Amgen became effective as of December 17, 2001. Under the Amgen agreement, Amgen paid the first $175.0 million of all authorized costs and expenses associated with the research, development and commercialization of Plenaxis products in the United States. Amgen's initial $175.0 million funding commitment was fulfilled during the third quarter of 2000. Following Amgen's completion of this funding, we became responsible for one-half of all subsequent United States research and development costs for Plenaxis products. Additionally, the agreement provided that following Amgen's completion of its $175.0 million funding commitment, we were required to reimburse Amgen for one-half of the costs associated with establishing a sales and marketing infrastructure for Plenaxis products in the United States. Through December 31, 2001, we recognized an aggregate of approximately $121.7 million of revenues under the Amgen agreement.

On August 19, 2002, we executed a termination agreement with Amgen. In accordance with this agreement, we made a final payment to Amgen of $13.0 million. This payment represented full and complete satisfaction of our share of the expenses incurred under the collaboration agreement, as well as consideration for the receipt from Amgen of full title to, and possession of, all materials inventory purchased during the term of the collaboration. As a result, we recognized a gain of $16.0 million during the third quarter of 2002.

Critical Accounting Policies

In December 2001, the Securities and Exchange Commission requested that all registrants discuss their most "critical accounting policies" in Management's Discussion and Analysis of Financial Condition and Results of Operations. The Commission indicated that a "critical accounting policy" is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this report, we believe the following accounting policies to be critical:

Use of Estimates. We prepare our financial statements in accordance with accounting principles generally accepted in the United States. These principles require that we make estimates and use assumptions that affect the reporting of our assets and our liabilities as well as the disclosures that we make regarding assets and liabilities and income and expense that are contingent upon uncertain factors as of the reporting date. The actual payments, and thus our actual results, could differ from our estimates.

Impairment or Disposal of Long-Lived Assets. Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* or SFAS No. 144, requires that

if the sum of the undiscounted future cash flows expected to result from a company's asset, net of interest charges, is less than the reported value of the asset, an asset impairment must be recognized in the financial statements. We evaluate our property, plant and equipment for impairment whenever indicators of impairment exist. The amount of the impairment to be recognized is calculated by subtracting the fair value of the asset from the reported value of the asset.

We believe that the application of SFAS No. 144 and the method used to determine the impairment of our property, plant and equipment involve critical accounting estimates because they are highly susceptible to change from period to period and because they require management to make assumptions about future cash flows, including residual values. In addition, we believe that had alternative assumptions been used the impact of recognizing an impairment on the assets reported on our balance sheet, as well as our net loss, may have been material.

We reviewed our building for impairment as of December 31, 2003. We have determined that the undiscounted sum of the expected future cash flows from the building exceeded the recorded value of the building. As a result, no impairment allowance was required in accordance with SFAS No. 144.

Management has discussed the development, selection and disclosure of these critical accounting policies with the audit committee of our board of directors.

Results of Operations

Years Ended December 31, 2003 and 2002

Revenues for the year ended December 31, 2003 were zero compared to approximately $1.0 million in 2002. During 2002 our revenues were comprised of a final reimbursement payment received in connection with the termination of our agreement with Sanofi-Synthélabo. We expect our only sources of revenues during 2004 to be from sales of Plenaxis in the United States and potential payments under foreign Plenaxis collaboration agreements, if consummated. We have previously forecast Plenaxis product revenues to be in the $10.0 million to $20.0 million range in 2004. We anticipate that these revenues will be heavily weighted towards the second half of 2004. Our actual revenues will depend upon a number of factors, including the impact of our risk management program, physician and patient acceptance of Plenaxis, the timing of reimbursement coverage and the overall success of our commercialization efforts.

Research and development expenses for the year ended December 31, 2003 decreased 26% to approximately $41.9 million, from approximately $56.4 million in 2002. The decrease in expenses reflects reduced spending in our clinical and preclinical programs. As a result of the resubmission of the Plenaxis NDA in February 2003, spending on the prostate cancer clinical development program was reduced significantly. We incurred no direct expenses in connection with our endometriosis program during 2003 pending a decision regarding further development, and do not expect any additional spending on this program for the foreseeable future. During the second quarter of 2003, we initiated a phase Ib clinical trial for Apan and expect to complete this study during the first half of 2004. We initiated a phase I clinical trial for PPI-2458 in patients with non-Hodgkin's lymphoma during the fourth quarter of 2003. In March 2004, the FDA placed this trial on clinical hold. Overall, we expect our research and development expenses to increase in 2004 and thereafter, primarily due to additional post-marketing studies for Plenaxis, preclinical and clinical studies for Apan and PPI-2458, and the expansion of our core technology platform, Direct Select. In addition, we currently have several other ongoing research and development programs.

While we are generally able to forecast our overall spending on research and development, we are unable to predict the precise level of spending on individual clinical programs due to the uncertain nature of clinical development and the potential for future development partnerships. Using industry estimates, typical drug development programs may last for ten or more years and may cost hundreds of millions of dollars to complete. As our programs progress, we will assess the possibility of entering into corporate collaborations to offset a portion of development costs. The ultimate success of our research and development programs and the impact of these programs on our operations and financial results

cannot be accurately predicted and will depend, in large part, upon the outcome and timing of many variables outside of our control.

Members of our research and development team typically work on a number of projects concurrently. In addition, a substantial amount of our fixed costs such as facility depreciation, utilities and maintenance are shared by our various programs. Accordingly, we have not and do not plan to specifically identify all costs related to each of our research and development programs. We estimate that during 2003 and 2002, the majority of our research and development expenses were related to manufacturing costs, clinical trial costs, salaries and lab supplies related to our prostate cancer, Alzheimer's disease and non-Hodgkin's lymphoma programs. The remaining research and development costs consisted primarily of salaries and lab supplies for our other research programs.

We began our clinical program to develop Plenaxis for the treatment of prostate cancer during 1996. In December 2000, we submitted an NDA to the FDA for Plenaxis for the treatment of hormonally responsive prostate cancer. However, the FDA raised concerns over the occurrence of immediate-onset, systemic allergic reactions observed in approximately 1.1% of all clinical trial patients dosed with Plenaxis. In addition, the FDA expressed concern that the effectiveness of Plenaxis in suppressing testosterone decreased with continued dosing in some patients. In November 2003, the FDA approved Plenaxis for the palliative treatment of men with advanced symptomatic prostate cancer, in whom LHRH agonist therapy is not appropriate and who refuse surgical castration, and have one or more of the following: (1) risk of neurological compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia. Plenaxis is not indicated for use in women or children. For safety reasons, Plenaxis was approved with marketing restrictions. Only physicians enrolled in the PLUS Program may prescribe Plenaxis.

In June 2003, we also submitted an MAA for Plenaxis in Germany. We believe that the German regulatory authorities will complete their review of our MAA during 2004. Assuming a favorable action, we plan to subsequently seek further European Union approval for Plenaxis under the MRP to market Plenaxis for the treatment of a broad population of hormonally responsive prostate cancer patients. We are in discussions with potential partners for the commercialization of Plenaxis in Europe, as well as for the development and/or commercialization of Plenaxis in Japan and other areas of the world. However, we cannot assure investors that we will be successful in obtaining approval abroad for the commercialization of Plenaxis for the treatment of any portion of the hormonally responsive prostate cancer patient population or for any other indication, or that we will be able to enter into collaboration agreements on favorable terms, if at all.

In 1998, we began our clinical program to develop Plenaxis for the treatment of endometriosis. We completed a phase II study of Plenaxis for the treatment of pain associated with endometriosis in March 2002. Analysis of the results of this study indicates that patients treated with Plenaxis experienced more bone mineral density loss than those treated with the comparator drug, and that this loss was dose-related. In order to better understand the bone mineral density loss, during 2002 and 2003 we conducted a pharmacokinetic study of Plenaxis for the treatment of endometriosis to determine the appropriate dose and dosing schedule necessary to maximize the benefit of the therapy for patients while minimizing attendant bone mineral density loss. The results of this study will be used as guidance for potential future clinical studies. We do not currently have any additional endometriosis studies planned and do not expect to conduct further studies without a corporate partner. Any additional development in endometriosis would also require consultation with the FDA.

We began our clinical program for Apan in 2000. We have completed a normal volunteer, phase Ia dose escalation study of Apan and have identified a maximum tolerated dose, or MTD, in healthy volunteers. During the second quarter of 2003, we initiated a phase Ib trial of Apan in Alzheimer's disease patients. In this trial, a single dose of Apan is administered, with the goal of establishing the MTD in patients. We anticipate completing this study during the first half of 2004. Upon completion of the phase Ib study and, assuming favorable FDA review of the study's results, we intend to initiate a

phase Ic trial examining multiple administrations of a selected Apan dose in Alzheimer's disease patients.

We initiated our first clinical study for PPI-2458 during the fourth quarter of 2003 in which an oral formulation of PPI-2458 is being evaluated in non-Hodgkin's lymphoma patients who are no longer benefiting from other therapies. In March 2004, the FDA placed this trial on clinical hold until questions relating to a neuropathological abnormality observed in some of the animals tested in a recently completed three-month animal safety study have been satisfactorily resolved. The results of this study were not available at the time that the clinical study was initiated. The FDA has indicated that we will need to submit a detailed plan in order to address this finding. We intend to further explore this finding to assess its potential implications and prepare a plan for the FDA. While we intend to work diligently with the FDA to resolve this issue, we cannot currently predict when the clinical hold will be released. We intend to continue evaluating the potential utility of PPI-2458 for treating certain other cancers, as well as certain autoimmune diseases.

Sales and marketing expenses for the year ended December 31, 2003 increased by approximately $3.4 million to approximately $5.2 million, from approximately $1.8 million in 2002. During 2003, we incurred increased sales and marketing expenses in preparation for the launch of Plenaxis in the United States. This was due to increased costs related to pre-commercialization efforts, in particular for market research, various physician and national meetings, pricing and reimbursement consulting, and sales force hiring and deployment activities. We promote Plenaxis in the United States through our own marketing and sales team. With the recent FDA approval of Plenaxis, we expect our sales and marketing expenses will increase during 2004 and will include expenses relating to the building of a marketing infrastructure, the cost of our sales force, commissions to the sales force on Plenaxis sales, and promotional and marketing programs.

General and administrative expenses for the year ended December 31, 2003 increased 3% to approximately $10.0 million, from approximately $9.7 million in 2002. We expect that general and administrative expenses will increase slightly during 2004 and thereafter based on normal hiring of additional administrative personnel to support continued growth of our commercialization initiatives and our research and development activities.

Net interest income for the year ended December 31, 2003 decreased 72% to approximately $1.3 million, from approximately $4.8 million in 2002. The decrease in net interest income was due primarily to lower average cash balances and reduced average interest rates.

The provision for income taxes for the years ended December 31, 2003 and 2002 was zero. We anticipate that we will continue to be in a net operating loss carryforward position for the next several years. Therefore, as in 2002, no benefit from our operating losses has been recognized. We account for income taxes under Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*. Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2003 and 2002, have been established in each period to reflect these uncertainties.

At December 31, 2003, we had federal net operating loss carryforwards of $170.3 million that will expire in varying amounts through 2023, if not utilized. Utilization of net operating loss and tax credit carryforwards will be subject to substantial annual limitations under the Internal Revenue Code of 1986, as amended. The annual limitations may result in the expiration of the net operating loss and tax credit carryforwards before full utilization.

Years Ended December 31, 2002 and 2001

Revenues for the year ended December 31, 2002 decreased to approximately $1.0 million, from approximately $9.9 million in 2001. The decrease in revenues was the result of the termination during the fourth quarter of 2001 of our collaboration agreements with Amgen and Sanofi-Synthélabo. During 2001 our revenues were comprised principally of reimbursement revenues under these agreements. During 2002 our revenues were comprised of a final reimbursement payment received in connection

with the termination of our agreement with Sanofi-Synthélabo. We will not receive any additional revenues under these agreements.

Research and development expenses for the year ended December 31, 2002 decreased 5% to approximately $56.4 million, from approximately $59.4 million in 2001. The slight decrease in expenses primarily reflects reduced spending in our Plenaxis prostate cancer clinical program and, to a lesser extent, the lack of spending on our clinical program for Latranal, an in-licensed compound that was in development for the treatment of musculoskeletal pain. Development of Latranal was discontinued during the third quarter of 2001. These decreases were partially offset by increased spending on preclinical studies related to our experimental drug candidate PPI-2458.

Sales and marketing expenses for the year ended December 31, 2002 decreased 79% to approximately $1.8 million, from approximately $8.7 million in 2001. During 2001, we incurred increased sales and marketing expenses in preparation for the potential launch of Plenaxis for the treatment of hormonally responsive advanced prostate cancer. The subsequent decrease in sales and marketing expenses was due to the temporary suspension of the majority of marketing efforts resulting from the repositioning of our prostate cancer program in response to issues raised by the FDA.

General and administrative expenses for the year ended December 31, 2002 increased 39% to approximately $9.7 million, from approximately $7.0 million in 2001. This increase was due primarily to higher facility-related expenses. In May 2001, we occupied our new, larger facility and began incurring depreciation expense and increased utilities, maintenance and tax expenses. In addition, higher personnel-related operating costs and increased professional services expenses contributed to the increase in general and administrative expenses. General and administrative expenses for 2002 and going forward fully reflect these new facility-related expenses.

Net interest income for the year ended December 31, 2002 decreased 48% to approximately $4.8 million, from approximately $9.1 million in 2001. The decrease in net interest income was due primarily to lower average cash balances and reduced average interest rates.

The provision for income taxes for the years ended December 31, 2002 and 2001 was zero. We anticipate that we will continue to be in a net operating loss carryforward position for the next several years. Therefore, no benefit from our operating losses in these years has been recognized.

Selected Quarterly Operating Results

The following table sets forth our unaudited statement of operations data for each of the eight quarters ended December 31, 2003. This information has been derived from our unaudited financial statements. The unaudited financial statements have been prepared on the same basis as the audited financial statements appearing in this report and include all adjustments, consisting only of normal recurring accruals, that we consider necessary for a fair presentation of such information when read in conjunction with our annual audited financial statements and notes thereto appearing elsewhere in this report. You should not draw any conclusions from the operating results for any quarter.

	Quarter Ended							
	Mar. 31, 2002	June 30, 2002	Sept. 30 2002(1)	Dec. 31, 2002	Mar. 31, 2003	June 30, 2003	Sept. 30, 2003	Dec. 31, 2003
	(in thousands, except per share data)							
Total revenues	$ —	$ 1,029	$ —	$ —	$ —	$ —	$ —	$ —
Operating loss	(13,890)	(15,506)	(22,585)	(14,886)	(11,831)	(15,928)	(13,093)	(16,295)
Net loss	(12,686)	(14,215)	(5,568)	(13,606)	(11,415)	(15,550)	(12,785)	(16,048)
Basic and diluted net loss per share	$ (0.25)	$ (0.27)	$ (0.11)	$ (0.26)	$ (0.22)	$ (0.30)	$ (0.25)	$ (0.31)

(1) In August 2002, we executed a termination agreement with Amgen and recognized a gain on termination of $16.0 million.

We expect to experience significant fluctuations in our quarterly operating results in the future, and, therefore, we will continue to have difficulty providing an accurate forecast of our quarterly

revenues and operating results. We believe that period-to-period comparisons of our operating results may not be meaningful, and you should not rely upon them as any indication of future performance. Operating results in one or more future quarters may be different from the expectations of securities analysts and investors. In the event that our operating results are lower than expectations, the trading price of our common stock would likely decline.

Liquidity and Capital Resources

To date, our operations and capital requirements have been financed primarily with the proceeds of public and private sales of common stock and preferred stock, payments under research and development partnerships and collaborative agreements, and investment income.

At December 31, 2003, we had cash, cash equivalents and marketable securities of approximately $143.2 million and working capital of approximately $133.0 million, compared to approximately $195.0 million and $185.5 million, respectively, at December 31, 2002. We expect our cash, cash equivalents and marketable securities at December 31, 2004 to range from approximately $60.0 million to $70.0 million. We believe that our existing cash and investments will be sufficient to meet our working capital and capital expenditure needs through approximately the end of 2005. Assuming the successful commercialization of Plenaxis in the United States, partnering of clinical programs at opportune times and continued prudent fiscal management, we believe that we should have sufficient financial resources to execute our operating plan and attain profitability by 2006.

For the year ended December 31, 2003, net cash of approximately $50.9 million was used in operating activities, compared to approximately $69.9 million used in operating activities during 2002. During the year ended December 31, 2003, our use of cash in operations was due principally to our net loss of approximately $55.8 million, partially offset by depreciation and amortization. During the year ended December 31, 2002, our use of cash in operations was due principally to our net loss of approximately $46.1 million, and our payment of $13.0 million in connection with the Amgen termination agreement, partially offset by depreciation and amortization. We expect our cash utilization to increase during 2004 as a result of an overall increase in operating expenses as we continue launch-related activities for Plenaxis, continue with clinical trials for Apan, continue preclinical and clinical trials for PPI-2458, and expand our research and development initiatives. We also expect a significant use of cash in relation to the production of inventory and buildup of accounts receivable related to Plenaxis. We expect to continue to utilize cash to increase the amount of inventory on hand through the end of fiscal year 2005 to support commercial sales of Plenaxis. The actual amount of these expenditures will depend on numerous factors, including the timing of expenses and the timing and progress of our research, development, marketing and sales efforts.

Net cash provided by investing activities of approximately $73.3 million in 2003 consisted of net sales of marketable securities of approximately $74.3 million and purchases of property and equipment of approximately $1.0 million. This compares to net cash used in investing activities of approximately $10.9 million during 2002. Net cash used in investing activities in 2002 consisted of purchases of property and equipment of approximately $1.8 million, and net purchases of marketable securities of approximately $9.1 million.

Our financing activities for the year ended December 31, 2003 consisted of approximately $0.6 million of proceeds received from the exercise of common stock options and approximately $0.4 million in principal repayments under our acquisition and construction loan agreement described below. Our financing activities for the year ended December 31, 2002 consisted of approximately $1.0 million of proceeds received from the exercise of common stock options.

In July 2000, in connection with the purchase, through our wholly owned real estate subsidiary, of our corporate headquarters and research facility in Waltham, Massachusetts, the subsidiary entered into an acquisition and construction loan agreement providing for up to $33.0 million in financing for the acquisition of, and improvements to, the facility. The loan is secured by the facility, together with all fixtures, equipment, improvements and other related items, and by all rents, income or profits received

by our real estate subsidiary, and is unconditionally guaranteed by us. As of December 31, 2003, approximately $32.6 million was outstanding under the loan agreement. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.12% at December 31, 2003). Principal and interest are payable monthly in arrears. In July, we exercised the first of two one-year extension options, extending the maturity date of the loan until July 30, 2004. As a result of this extension, in August 2003 we started making monthly principal payments on the loan of approximately $62,000, in addition to interest payments. In connection with this extension, we also entered into an interest rate cap agreement in order to reduce the potential impact of interest rate increases on future income. During 2004, we expect to either exercise the second one-year extension option available to us or refinance the debt instrument for a longer term.

In addition to our long-term debt, we have fixed purchase obligations under various supply agreements. As of December 31, 2003, our long-term debt and fixed purchase obligations were as follows:

		Payments Due By Period			
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	After 5 Years
		(in thousands)			
Long-term debt obligations	$32,627	$ 747	$31,880	$ —	$ —
Unconditional purchase obligations (1)	3,117	1,167	1,300	650	—
Total	$35,744	$1,914	$33,180	$650	$ —

(1) In January 2004, we agreed with Cambrex Charles City, Inc. to a minimum purchase commitment of $792,000 for 2004. In addition, based upon the first commercial shipment of Plenaxis made in January 2004, our minimum annual purchase commitment from Baxter Pharmaceutical Solutions LLC will increase to $650,000 in 2005. These amounts are reflected in the table above.

At December 31, 2003, we had provided a valuation allowance of $86.5 million for our deferred tax assets. The valuation allowance represents the value of the deferred tax assets. Due to anticipated operating losses in the future, we believe that it is more likely than not that we will not realize the net deferred tax assets in the future and we have provided an appropriate valuation allowance.

Recent Accounting Pronouncements

On December 31, 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure,* or SFAS No. 148. SFAS No. 148 amends Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and Accounting Principles Board Opinion No. 28, *Interim Financial Reporting*, to include increased pro-forma disclosure of the effects of stock-based employee compensation on the results of operations. SFAS No. 148 became effective for fiscal years ending after December 15, 2002. The Company has elected to continue to account for employee stock-based compensation using the intrinsic value method as described in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and therefore, the adoption of SFAS No. 148 did not have a material impact on our consolidated results of operations in 2003.

In January 2003, the Financial Accounting Standards Board issued Financial Accounting Standards Board Interpretation No. 46, *Consolidation of Variable Interest Entities*, or FIN No. 46. FIN No. 46 sets forth the criteria used in determining whether an investment in a variable interest entity, or VIE, should be consolidated and is based on the general premise that companies that control another entity through interests other than voting interests should consolidate the controlled entity. We do not have any VIE's. Accordingly, the implementation of FIN No. 46 will not have any impact on our consolidated financial statements.

In May 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, or SFAS No. 150. SFAS No. 150 establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies. The Financial Accounting Standards Board has indefinitely deferred implementation of some provisions of SFAS No. 150. We believe that the adoption of SFAS No. 150 will not have a material impact on our consolidated financial statements.

Risk Factors that May Affect Future Results

The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that are currently deemed immaterial may also impair our business, financial condition and results of operations. If any of these risks actually occur, our business, financial condition and results of operations could be materially adversely affected.

We have a history of losses and anticipate significant increases in our operating expenses over the next several years, and we may not be profitable in the future.

We cannot assure you that we will be profitable in the future or, if we attain profitability, that it will be sustainable. In November 2003, we received FDA approval to market Plenaxis for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration. All of our other product candidates are in the research or development stage. Sales of Plenaxis began in January 2004. Prior to the launch of Plenaxis, we had never marketed or sold any products, and we may not succeed in marketing or selling Plenaxis, or developing and marketing any product in the future. To date, we have derived substantially all of our revenues from payments under corporate collaboration and license agreements. We expect to continue to spend significant amounts to further develop our commercial sales and marketing capabilities, continue clinical studies and seek regulatory approval for our other product candidates. We also intend to spend substantial amounts to fund additional research and development for other potential products, enhance our core technologies, and for general and administrative purposes. As of December 31, 2003, we had an accumulated deficit of approximately $186.3 million. We expect that our operating expenses will increase significantly due primarily to increased expenses related to continued commercialization activities for Plenaxis, as well as the initiation and continuation of studies as part of our other clinical programs, resulting in significant operating losses at least through 2005. We currently do not expect to achieve profitability until 2006 at the earliest. Moreover, our ability to attain profitability by 2006 is dependent on numerous factors, including our ability to successfully commercialize Plenaxis in the United States, partnering of clinical programs at opportune times and continued prudent fiscal management. Even if we do become profitable, we cannot assure you that we would be able to sustain or increase profitability on a quarterly or annual basis.

Our business is dependent on the commercial success of Plenaxis. If Plenaxis fails to achieve market acceptance, it may never be commercially successful and we may be unable to continue our operations as planned.

The success of our business is dependent on the successful commercialization of Plenaxis. Plenaxis is new to the market and may be unfamiliar to members of the medical community and to patients. Market acceptance will depend largely on our ability to demonstrate, to the oncology and urology communities in particular, the efficacy and safety of Plenaxis as an alternative to currently marketed therapies or surgical options. We cannot be certain that Plenaxis will provide benefits considered adequate by providers of oncology and urology services or that enough providers will use the product

to ensure its commercial success. Many factors may affect its market acceptance and commercial success of Plenaxis, including:

- the scope of the patient population and the indication for which Plenaxis was approved;
- the terms of the risk management program required by the FDA in connection with the approval of Plenaxis;
- the product labeling and product insert required by the FDA;
- the effectiveness of Plenaxis and the potential side effects, including the risk of immediate-onset systemic allergic reactions, as compared to alternative treatment methods;
- the extent and success of our marketing and sales efforts;
- the cost-effectiveness of Plenaxis and the availability of insurance or other third-party reimbursement, in particular Medicare, for patients, and the rate of such reimbursement;
- the competitive features of Plenaxis as compared to other products or treatment options, including the frequency of administration of Plenaxis as compared to other products, and doctor and patient acceptance of these features; and
- unfavorable publicity concerning Plenaxis or any similar products.

In addition, we must continually submit any labeling, advertising and promotional material to the FDA for review and pre-approval. There is risk that the FDA will prohibit use of the marketing material in the form we desire. Unfavorable outcomes resulting from factors such as those identified above could limit sales of Plenaxis or cause sales of Plenaxis to decline. In those circumstances, we may have to find additional sources of funding or scale back or cease operations. If Plenaxis is not commercially successful, we may be unable to continue our operations as planned.

We may be unable to establish marketing and sales capabilities necessary to successfully commercialize Plenaxis or our other potential products.

We have no experience in marketing or selling pharmaceutical products and have limited marketing and sales resources. To achieve commercial success for Plenaxis, or any other approved product, we must either develop a marketing and sales force, as well as the infrastructure to support it, or enter into arrangements with others to market and sell our products. We have determined to promote Plenaxis in the United States through our own dedicated marketing and sales team. Recruiting and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we cannot assure you that we will be able to attract and retain a sufficient number of qualified individuals to successfully launch Plenaxis. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Plenaxis.

In addition, establishing the expertise necessary to successfully market and sell Plenaxis, or any other product, will require a substantial capital investment. Our ability to make that investment and also execute our current operating plan and attain profitability by 2006 is dependent on numerous factors, including, as described above, partnering of clinical programs at opportune times and continued prudent fiscal management. Accordingly, we cannot assure investors that we will have the funds to successfully commercialize Plenaxis or any other potential product in the United States or elsewhere.

Moreover, Plenaxis competes, and our product candidates in development are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales operations. Because these companies are capable of devoting significantly greater resources to their marketing and sales efforts, our marketing and sales efforts may not compete successfully against the efforts of these other companies.

We have also announced our intention to market and sell Plenaxis outside of the United States through one or more marketing partners upon receipt of approval abroad. We have not entered into any such arrangements and we cannot assure you that we will be able to enter into agreements with third parties on acceptable terms, if at all. In addition, co-promotion or other marketing arrangements with third parties to commercialize Plenaxis or any other potential products could significantly limit the revenues we derive from these products, and these third parties may fail to commercialize Plenaxis or our other potential products successfully. To the extent we enter into any such agreements, the parties to those agreements may also market products that compete with our products, further limiting our potential revenue from product sales.

Alternative treatment options exist and may be more readily available or acceptable to physicians and patients, which may impair our ability to capture or maintain market share for Plenaxis.

Alternative products and medical treatments exist or are under development to treat advanced symptomatic prostate cancer. For example, the FDA has approved several drugs for the treatment of prostate cancer that respond to changes in hormone levels, and there are other treatment alternatives available, including radiation therapy and surgery. The FDA's approval of Plenaxis is limited to use in a subset of advanced symptomatic prostate cancer patients, and distribution of Plenaxis will only be made in accordance with our risk management program, which includes physician enrollment in a prescribing program and a signed patient consent form regarding the risks and benefits of the therapy. Due to the potential risk of immediate-onset systemic allergic reactions, physicians must also monitor patients for 30 minutes following the injection of Plenaxis. Prescribing physicians and patients may view these requirements as burdensome or may recommend or choose to use alternative treatments that are more readily available or more acceptable to the doctor and/or the patient. If, due to these factors, Plenaxis does not achieve broad market acceptance as a drug for the treatment of the symptoms of men with advanced prostate cancer for whom other hormonal therapies are not appropriate and who have refused surgical castration, we may be unable to continue our operations as planned.

Our potential revenues will diminish if we fail to obtain adequate reimbursement coverage for Plenaxis or our other product candidates from third-party payors.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payors do not provide appropriate coverage and adequate reimbursement for Plenaxis or our other product candidates, physicians may not prescribe them. Additionally, physicians may not prescribe Plenaxis if we fail to provide adequate education about its benefits and uses. In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. In addition, managed care initiatives in the United States will continue to put pressure on the pricing of pharmaceutical products.

Our ability to earn revenues from Plenaxis, or any other potential product, alone or with collaborators, may depend in part on the availability and levels of reimbursement from:

- government and health administration authorities, including Medicare and Medicaid;
- private health insurers; and
- other third-party payors.

We cannot predict the availability of coverage or reimbursement for newly approved drugs such as Plenaxis by Medicare or any other payor. Third-party payors, including Medicare, are increasingly challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs and, in some cases, refusing to provide coverage for a patient's use of an approved drug for purposes not

approved by the FDA. Third-party insurance coverage may not be available to patients for Plenaxis or any of our other products.

We may experience pressure to lower the price of Plenaxis or our other potential products because of new and/or proposed federal legislation.

New federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs covered by Medicare are reimbursed, generally leading to lower reimbursement levels. The new legislation has also added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. While the new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the United States government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices.

As Plenaxis is used commercially, unintended side effects or adverse reactions could occur that could result in additional regulatory controls and reduced sales.

During research and development, the use of pharmaceutical products, such as Plenaxis, is limited principally to clinical trial patients under controlled conditions and under the care of expert physicians. The widespread commercial use of Plenaxis could produce undesirable or unintended side effects that have not been evident in our clinical trials. In addition, in patients who take multiple medications, drug interactions could occur that can be difficult to predict. These events, among others, could result in the imposition of additional regulatory controls that could limit the circumstances under which Plenaxis is prescribed or even lead to the withdrawal of the product from the market. Due to the occurrence of immediate-onset systemic allergic reactions in patients treated with Plenaxis during clinical trials, Plenaxis has been approved under regulations concerning drugs with certain safety profiles, under which the FDA has established special restrictions to ensure safe use. Post-marketing phase IV studies are also required to evaluate the incidence of and further characterize such allergic reactions to the extent they occur. Any violation of these special restrictions or unfavorable findings in the phase IV studies could lead to the imposition of further restrictions or withdrawal of Plenaxis from the market.

If we fail to develop and maintain our relationships with third-party manufacturers, or if these manufacturers fail to perform adequately, we may be unable to commercialize Plenaxis or any of our product candidates.

Our ability to conduct, or continue to conduct, clinical trials and commercialize Plenaxis or other product candidates, will depend in part on our ability to manufacture, or arrange for third-party manufacture of, our products on a large scale, at a competitive cost and in accordance with regulatory requirements. We must establish and maintain a commercial scale formulation and manufacturing process for each of our potential products for which we seek marketing approval. We or third-party manufacturers may encounter difficulties with these processes at any time that could result in delays in clinical trials, regulatory submissions or in the commercialization of potential products.

We have no experience in large-scale product manufacturing, nor do we have the resources or facilities to manufacture products on a commercial scale. We will continue to rely upon contract manufacturers to produce Plenaxis and other compounds for later-stage preclinical, clinical and commercial purposes for a significant period of time. Third-party manufacturers may not be able to meet our needs as to timing, quantity or quality of materials. If we are unable to contract for a

sufficient supply of needed materials on acceptable terms, or if we encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby preventing or delaying the submission of product candidates for, or the granting of, regulatory approval and the commercialization of our potential products. Any such delays may lower our revenues and delay or prevent our attaining or maintaining profitability.

If the third-party manufacturers upon which we rely fail to meet our needs for clinical or commercial supply, we may be required to supplement our manufacturing capacity by building our own manufacturing facilities. This would require substantial expenditures. Also, we would need to hire and train significant numbers of employees to staff a new facility. If we are required to build our own facility, we may not be able to develop sufficient manufacturing capacity to produce drug materials for clinical trials or commercial use.

In addition, we and the third-party manufacturers that we use must continually adhere to current good manufacturing practice requirements enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, the FDA pre-market approval of our product candidates will not be granted. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory sanctions, and the facilities could be shut down.

Any of these factors could prevent, or cause delays in, obtaining regulatory approvals for our potential products, and the manufacturing, marketing or selling of Plenaxis, and could also result in significantly higher operating expenses.

The loss or failure of any of our third-party manufacturers could substantially delay or impair our sale or continued sale of Plenaxis.

For each stage of Plenaxis production we have relied, and expect in the near term to continue to rely, on a single third-party manufacturer, and we currently have not contracted, and in the near term do not expect to contract, with a second supplier for any of these production stages. Accordingly, the loss of one or more of these suppliers for any reason, including as a result of fire, terrorism, acts of God or insolvency or bankruptcy, could result in substantial delays in, or substantially impair our ability to complete, clinical trials and regulatory submissions or reviews, and could delay or impair substantially our sale or continued sale of Plenaxis. Such delays or impairment, and the associated costs and expenses, may lower our potential revenues and delay or prevent our attaining profitability. While we are evaluating the possibility of a second source of supply at certain stages of Plenaxis production, the number of qualified alternative suppliers is limited, and we cannot assure investors that we will be able to locate alternative suppliers or negotiate second supply agreements on reasonable terms. Furthermore, the process of engineering a new supplier's facility for the production of Plenaxis and obtaining the necessary FDA approval of the facility would require substantial lead-time and could be extremely costly. We cannot assure investors that we will not lose one or more of our suppliers, or that in such event we would be readily able to continue the commercialization of Plenaxis without substantial and costly delays.

We are subject to extensive government regulation that increases our costs and could prevent us from selling Plenaxis or our other potential products.

The development and sale of Plenaxis, and our product candidates, is subject to extensive regulation by governmental authorities. Obtaining and maintaining regulatory approval typically is costly and takes many years. Regulatory authorities, most importantly, the FDA, have substantial discretion to place on clinical hold or terminate clinical trials, delay, withhold or withdraw registration and marketing approval in the United States, and effectively mandate product recalls. Failure to comply with

regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions as to Plenaxis, our other potential products or against us. Outside the United States, we can market a product only if we receive marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with the FDA approval process, and may include additional risks.

To gain regulatory approval from the FDA and foreign regulatory authorities for the commercial sale of any product, we must demonstrate in clinical trials, and satisfy the FDA and foreign regulatory authorities as to, the safety and efficacy of the product. If we develop a product to treat a long-lasting disease, such as cancer or Alzheimer's disease, we must gather data over an extended period of time. There are many risks associated with our clinical trials. For example, we may be unable to achieve the same level of success in later trials as we did in earlier ones. Additionally, data we obtain from preclinical and clinical activities are susceptible to varying interpretations that could impede regulatory approval. Further, some patients in our prostate cancer, Alzheimer's disease and non-Hodgkin's lymphoma programs have a high risk of death, age-related disease or other adverse medical events that may not be related to our products. These events may affect the statistical analysis of the safety and efficacy of our products. If we obtain regulatory approval for a product, the approval will be limited to those diseases for which our clinical trials demonstrate the product is safe and effective.

In addition, many factors could delay or result in termination of our ongoing or future clinical trials. For example, results from ongoing preclinical studies or analyses could raise concerns over the safety or efficacy of a product candidate. The FDA recently placed our phase I clinical trial of PPI-2458 on clinical hold due to a neuropathological abnormality observed in some of the animals tested in a recently completed three-month animal safety study. The FDA has indicated that we will need to submit a detailed plan in order to address this finding. We intend to further explore this finding to assess its potential implications and prepare a plan for the FDA. While we intend to work diligently with the FDA to resolve this issue, we cannot currently predict when the clinical hold will be released. A clinical trial may also experience slow patient enrollment or lack of sufficient drug supplies. Patients may experience adverse medical events or side effects, and there may be a real or perceived lack of effectiveness of, or of safety issues associated with, the drug we are testing. Future governmental action or existing or changes in FDA policies or precedents, may also result in delays or rejection of an application for marketing approval. The FDA has considerable discretion in determining whether to grant marketing approval for a drug, and may delay or deny approval even in circumstances where the applicant's clinical trials have proceeded in compliance with FDA procedures and regulations and have met the established end-points of the trials. Challenges to FDA determinations are generally time-consuming and costly, and rarely, if ever succeed. In November 2003, we received FDA approval to market Plenaxis in the United States. We can give no assurance that we will obtain marketing approval for any of our other product candidates.

Any regulatory approval may be conditioned upon significant labeling requirements and, as in the case of the FDA approval of Plenaxis, marketing restrictions and post-marketing study commitments. Such labeling and marketing restrictions could materially adversely affect the marketability or value of a product, including Plenaxis, resulting in decreased sales. In such a case, we may have insufficient funds to continue operations as currently planned.

In addition, even after regulatory approval is obtained, our Company, product and the manufacturing facilities for our product will be subject to continual review and periodic inspection. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, the manufacturer or us, including withdrawal of the product from the market. The FDA stringently applies regulatory standards. Our manufacturing facilities will also be subject to FDA inspections for adherence to good manufacturing practices prior to marketing clearance and periodically during the manufacturing process. Failure to comply can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions,

injunctions and criminal prosecution. If there are any modifications to a product, further regulatory approval will be required.

For safety reasons, Plenaxis was approved by the FDA with a comprehensive risk management program. This program includes educational outreach to patients and physicians regarding the risks and benefits of Plenaxis, restricted distribution of the product only to physicians enrolled in a prescribing registry, a system for collecting and reporting adverse events to the FDA and auditing requirements to evaluate the effectiveness of the program. We are also required to conduct several phase IV studies to evaluate the risk management program and the appropriate use of the drug in the indicated population. Under the regulations under which Plenaxis was approved, the FDA has the authority to pre-approve all promotional materials and has available to it an expedited market withdrawal procedure if issues arise regarding the safe use of Plenaxis. If approval for Plenaxis is withdrawn, we will not be able to sell Plenaxis and may have insufficient funds to continue operations as currently planned.

If we are unable to maintain FDA approval, or to obtain any foreign regulatory approval for Plenaxis, or to obtain or maintain regulatory approval to market our other potential products, we may exhaust our available resources significantly sooner than we had planned. If this were to happen, we would need to either raise additional funds or seek partners to continue our currently planned research and development programs. We cannot assure you that we would be able to raise the necessary funds or negotiate additional corporate collaborations on acceptable terms, if at all.

We rely upon a limited number of pharmaceutical specialty distributors that could impact the ability to sell Plenaxis.

In the United States, we rely upon a limited number of specialty distributors to deliver Plenaxis to physicians and hospital pharmacies. There are a relatively small number of specialty distributors and wholesalers who provide such services. These distributors must also distribute Plenaxis only to physicians and hospital pharmacists enrolled in our risk management program. There can be no assurances that these distributors will adequately provide their services to either the end users or to the Company.

Because we depend on third parties to conduct laboratory testing and human clinical studies and assist us with regulatory compliance, we may encounter delays in product development and commercialization.

We have contracts with a limited number of research organizations to design and conduct our laboratory testing and human clinical studies. If we cannot contract for testing activities on acceptable terms, or at all, we may not complete our product development efforts in a timely manner. To the extent we rely on third parties for laboratory testing and human clinical studies, we may lose some control over these activities. For example, third parties may not complete testing activities on schedule or when we request them to do so. In addition, these third parties may conduct our clinical trials in a manner inconsistent with regulatory requirements or otherwise in a manner that yields misleading or unreliable data. This, or other failures of these third parties to carry out their duties, could result in significant additional costs and expenses and could delay or prevent the development and commercialization of our product candidates.

Many of our competitors have substantially greater resources than we do and may be able to develop and commercialize products that make our potential products and technologies obsolete or non-competitive.

A biopharmaceutical company such as ours must keep pace with rapid technological change and faces intense competition. We compete with biotechnology and pharmaceutical companies for funding, access to new technology, research personnel and in product research and development. Many of these companies have greater financial resources and more experience than we do in developing drugs, obtaining regulatory approvals, manufacturing, marketing and sales. We also face competition from

academic and research institutions and government agencies pursuing alternatives to our products and technologies. We expect that Plenaxis, and all of our products under development, will face intense competition from existing or future drugs and other medical treatments. In addition, for each of our product candidates, we may face increasing competition from generic formulations or existing drugs whose active components are no longer covered by patents.

Our competitors may:

- successfully identify drug candidates or develop products earlier than we do;
- obtain approvals from the FDA or foreign regulatory bodies more rapidly than we do;
- develop products that are more effective, have fewer side effects or cost less than our products; or
- successfully market and sell products that compete with our products.

The success of our competitors in any of these efforts would adversely affect our ability to promote Plenaxis and to develop and commercialize our product candidates, and to ultimately attain and maintain profitability.

If we are unable to obtain and enforce valid patents, we could lose any competitive advantage we may have.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of our technologies and potential products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode any competitive advantage we may have. For example, if we lose our patent protection for Plenaxis, another party could produce and market the compound in direct competition with us. Some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in foreign countries.

Patent positions are sometimes uncertain and usually involve complex legal and factual questions. We can protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We currently own or have exclusively licensed 27 issued United States patents. We have applied, and will continue to apply, for patents covering both our technologies and products as we deem appropriate. Others may challenge our patent applications or our patent applications may not result in issued patents. Moreover, any issued patents on our own inventions, or those licensed from third parties, may not provide us with adequate protection, or others may challenge the validity of, or seek to narrow or circumvent, these patents. Third-party patents may impair or block our ability to conduct our business. Additionally, third parties may independently develop products similar to our products, duplicate our unpatented products, or design around any patented products we develop.

If we are unable to protect our trade secrets and proprietary information, we could lose any competitive advantage we may have.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If these measures do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques, which could impair any competitive advantage we may have.

If our technologies, processes or products conflict with the patents or other intellectual property rights of competitors, universities or others, we could have to engage in costly litigation and be unable to commercialize those products.

Our technologies, processes, product or product candidates may give rise to claims that they infringe patents or other intellectual property rights of third parties. A third party could force us to pay damages, stop our use of these technologies or processes, or stop our manufacturing or marketing of the affected products by bringing a legal action against us for infringement. In addition, we could be required to obtain a license to continue to use the technologies or processes or to manufacture or market the affected products, and we may not be able to do so on acceptable terms or at all. We believe that significant litigation will continue in our industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources. Even if legal actions were meritless, defending a lawsuit could take significant time, be expensive and divert management's attention from other business concerns.

If third parties terminate our licenses, we could experience delays or be unable to complete the development and commercialization of our potential products.

We license some of our technology from third parties. Termination of our licenses could force us to delay or discontinue some of our development and commercialization programs. For example, if Advanced Research and Technology Institute, Inc., the assignee of Indiana University Foundation, terminated our license with them, we could have to discontinue the commercialization of Plenaxis. We cannot assure you that we would be able to license substitute technology in the future. Our inability to do so could impair our ability to conduct our business because we may lack the technology, or the necessary rights to technology, required to develop and commercialize our potential products.

We may have substantial exposure to product liability claims and may not have adequate insurance to cover those claims.

The administration of drugs to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs are actually at fault for causing an injury. As Plenaxis is used more widely, the likelihood of an adverse drug reaction (both expected or unexpected) or unintended side effect will increase. Furthermore, Plenaxis or our product candidates may cause, or may appear to have caused, adverse side effects (including death) or potentially dangerous drug interactions that we may not learn about or understand fully until the drug has been administered to patients for some time.

Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance. The costs of product liability insurance have increased dramatically in recent years, and the availability of coverage has decreased. Although the Company carries insurance that it regards as reasonably adequate to protect it from potential claims, there can be no assurance that the Company will be able to maintain its current product liability insurance at a reasonable cost, or at all. Our collaboration agreements with Amgen and Sanofi-Synthélabo included, and the agreements with them regarding the termination of those collaborations also include, an indemnification of them for liabilities associated with the development and commercialization of Plenaxis. If a third party, including a former collaborator, successfully sues us for any injury, or for indemnification for losses, there is no guarantee that the amount of the claim would not exceed the limit of the Company's insurance coverage. Further, a successful claim could result in the recall of Plenaxis, or could reduce revenues from sales of Plenaxis. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with our business.

Pharmaceutical companies have been the target of lawsuits and investigations and there is no assurance that if we were to be involved in any such lawsuits or investigation, that our defense would be successful.

Pharmaceutical companies have been the target of lawsuits and investigations including, in particular, claims asserting violations of the Federal False Claim Act, Anti-Kickback Act, the Prescription Drug Marketing Act or other violations in connection with Medicare and/or Medicaid reimbursement, and claims under state laws, including state anti-kickback and fraud laws. Public companies may also be the subject of certain other types of claims, including those asserting violations of securities laws or related to environmental matters. There is no assurance that if we were to be involved in any such lawsuits or investigation, that we would be successful in defending ourselves or in asserting our rights.

If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to pursue our product development and commercialization efforts.

We depend substantially on the principal members of our management and scientific staff, including Malcolm L. Gefter, Ph.D., our Chief Executive Officer and Chairman of the Board, and William K. Heiden, our President and Chief Operating Officer. We do not have employment agreements with any of our executive officers. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

Recruiting and retaining qualified scientific personnel to perform future research and development work also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We compete with numerous companies and academic and other research institutions for experienced scientists. This competition may limit our ability to recruit and retain qualified personnel on acceptable terms. Failure to attract and retain qualified personnel would prevent us from continuing to develop our potential products, enhancing our technologies and launching our products commercially. Our planned activities will require the addition of new personnel, including management and marketing and sales personnel, and the development of additional expertise by existing management personnel, in particular in the area of product marketing and sales. The inability to attract and retain these people or to develop this expertise could prevent, or result in delays in, the marketing and sale of Plenaxis or the research, development and commercialization of our product candidates.

We use hazardous chemicals and radioactive and biological materials in our business and any claims relating to the handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials, which may pose health risks. For example, the health risks associated with accidental exposure to Plenaxis include temporary impotence or infertility and harmful effects on pregnant women. Our operations also produce hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge from hazardous materials and any resultant injury. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. Compliance with health and safety and environmental laws and regulations is necessary and expensive. Current or future health and safety and environmental regulations may impair our research, development or production efforts. We may be required to pay fines, penalties or damages in the event of noncompliance or the exposure of individuals to hazardous materials.

From time to time, third-parties have also worked with hazardous materials in connection with our agreements with them. We have agreed to indemnify our present and former collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

The market price of our common stock may experience extreme price and volume fluctuations.

The market price of our common stock may fluctuate substantially due to a variety of factors, including, but not limited to:

- our ability to successfully commercialize Plenaxis in the United States;
- failure or delay by third-party manufacturers in performing their supply obligations or disputes or litigation regarding those obligations;
- the availability of reimbursement coverage for Plenaxis and changes in the reimbursement policies of third-party insurance companies or government agencies;
- our ability to enter into foreign corporate collaborations for Plenaxis, or United States or foreign corporate collaborations for our other product candidates, and the timing and terms of such collaborations;
- the success rate of our discovery efforts and clinical trials;
- announcement of FDA approval or disapproval of any of our product candidates, or of associated labeling requirements;
- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights, including claims of infringement, interference or litigation against us or our licensors;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industry in general;
- public concerns as to the safety of Plenaxis or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In addition, the stock market has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology companies, particularly companies like ours without current product revenues and earnings, have been highly volatile, and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources.

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- expected or unexpected fluctuations in Plenaxis revenues;
- the timing and level of expenses related to the commercialization of Plenaxis;

- the timing and level of expenses related to our other research and clinical development programs; and
- the timing of our commercialization of other products resulting in revenues.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

If we engage in an acquisition, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

If appropriate opportunities become available, we may attempt to acquire businesses, or acquire or in-license products or technologies, that we believe are a strategic fit with our business. We currently have no commitments or agreements for any acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired business, or an acquired or in-licensed product or technology, may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, we may fail to realize the anticipated benefits of any transaction of this sort. To the extent we issue stock in a transaction, the ownership interest of our stockholders will be diluted. Transactions of this kind could also cause us to incur debt, expose us to future liabilities and result in expenses related to goodwill and other intangible assets.

Anti-takeover provisions in our charter and by-laws, our rights agreement and certain provisions of Delaware law may make an acquisition of us more difficult, even if an acquisition would be beneficial to our stockholders.

Provisions in our certificate of incorporation and by-laws may delay or prevent an acquisition of us or a change in our management. Also, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit or delay large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. In addition, the rights issued under our rights agreement may be a substantial deterrent to a person acquiring 10% or more of our common stock without the approval of our board of directors. These provisions in our charter and by-laws, rights agreement and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. We have not entered into any instruments for trading purposes. Some of the securities that we invest in may have market risk. This means that an increase in prevailing interest rates may cause the principal amount of the investment to decrease. To minimize this risk in the future, we maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and government and non-government debt securities. An immediate hypothetical 100 basis point increase in interest rates would have resulted in an approximate $0.3 million decrease in the fair value of our investments as of December 31, 2003. The same hypothetical increase in interest rates as of December 31, 2002 would have resulted in an approximate $0.8 million decrease in the fair value of our investments. Due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. As of December 31, 2003, approximately 71% of our total portfolio will mature in one year or less, with the remainder maturing in less than three years.

In connection with the purchase of our new facility in July 2000, our wholly owned real estate subsidiary executed an acquisition and construction loan agreement that provides for up to $33.0 million in borrowings at a floating interest rate indexed to 30-day LIBOR. Concurrent with that

transaction, the subsidiary also entered into an interest rate cap agreement which limits exposure to interest rate increases above a certain threshold. Due to the decrease in interest rates since we entered into this interest rate cap, we currently do not believe that there is material interest rate risk exposure with respect to the loan agreement. In addition, we believe that we have mitigated our risk relating to significant adverse fluctuations in interest rates with respect to borrowings under the loan agreement, and we do not believe that a 10% change in interest rates would have a material impact on our results of operations or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required by this Item are included on pages F-1 through F-18 of this report. The supplementary financial information required by this Item is included in the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations," under the heading "Selected Quarterly Operating Results."

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of our chief executive officer and chief financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on such evaluation, the Company's chief executive officer and chief financial officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable SEC rules and forms.

(b) Internal Control Over Financial Reporting.

There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information required by this Item with respect to our code of ethics can be found in Item 1 of this report under the heading "Available Information." Information required by this Item with respect to directors, executive officers, the Company's audit committee and compliance with Section 16(a) of the Securities Act of 1934, as amended, may be found in the sections captioned "Nominees for Election to the Board of Directors," "Executive Officers Who Are Not Directors," "Board Actions; Committees of the Board of Directors—Audit Committee" and "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004. Such information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this Item may be found in the sections captioned "Director Compensation," "Executive Compensation and Other Information," "Compensation Committee Interlocks and Insider Participation," "Compensation Committee Report on Executive Compensation" and "Stockholder Return Performance Presentation" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004. Such information is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Information required by this Item may be found in the sections captioned "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004. Such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information required by this Item may be found in the section captioned "Certain Relationships and Related Transactions" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Information required by this Item may be found in the section captioned "Independent Auditor Fees" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 13, 2004. Such information is incorporated herein by reference.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Consolidated Financial Statements located on page F-1, which immediately follows the signature page of this report.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit No.	Exhibit
3.1	Amended and Restated Certificate of Incorporation (2)
3.2	Third Amended and Restated By-Laws (11)
4.1	Specimen certificate representing shares of common stock (1)
4.2	Specimen certificate representing shares of common stock (including Rights Agreement Legend) (5)
4.3	Rights Agreement between PRAECIS and American Stock Transfer & Trust Company, as Rights Agent (6)
4.4	Form of Certificate of Designations of Series A Junior Participating Preferred Stock (attached as Exhibit A to the Rights Agreement filed as Exhibit 4.3 hereto) (6)
4.5	Form of Rights Certificate (attached as Exhibit B to the Rights Agreement filed as Exhibit 4.3 hereto) (6)
10.1*	Second Amended and Restated 1995 Stock Plan (3)
10.2*	Amendment No. 1 to the Second Amended and Restated 1995 Stock Plan (8)
10.3*	Executive Management Bonus Plan, as amended and restated as of September 12, 2002 (10)
10.4*	Amended and Restated Employee Stock Purchase Plan (12)
10.5*	Management Incentive Program (11)
10.6*	Amended and Restated Stockholders Agreement dated as of April 30, 1998 by and among PRAECIS and certain stockholders referred to therein, as amended by Amendment No. 1 dated as of May 14, 1998, Amendment No. 2 dated as of July 21, 1998 and Amendment No. 3 dated as of January 31, 2000 (1)
10.7*	Amendment No. 4 dated as of September 1, 2000 to Amended and Restated Stockholders Agreement dated as of April 30, 1998 by and among PRAECIS and certain stockholders referred to therein, as amended (4)
10.8*	Letter Agreement dated as of May 9, 2002 between PRAECIS and William K. Heiden (9)
10.9*	Promissory Note dated May 16, 2002 executed by William K. Heiden in favor of PRAECIS (9)
10.10*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Malcolm L. Gefter, Ph.D. (9)
10.11*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Kevin F. McLaughlin (9)
10.12*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Marc B. Garnick, M.D. (9)
10.13†	License Agreement effective as of October 17, 1996 by and between PRAECIS and Indiana University Foundation, as amended as of June 3, 1998 (1)
10.14†	Supply Agreement dated as of July 23, 1998 by and between PRAECIS and Salsbury Chemicals, Inc. (1)
10.15†	Development and Supply Agreement effective as of June 21, 2000 by and between UCB S.A. and Amgen Inc., as amended by Amendment No. 1 thereto dated as of March 26, 2002 (together with the Assignment of Development and Supply Agreement entered into January 18, 2002 and effective as of December 17, 2001 by and between Amgen Inc. and PRAECIS) (7)

Exhibit No.	Exhibit
10.16†	Commercial Supply Agreement dated December 4, 2002 and effective as of June 1, 2002 by and between Baxter Pharmaceutical Solutions LLC and PRAECIS (11)
10.17	Termination Agreement dated as of August 19, 2002 by and between PRAECIS and Amgen Inc. (10)
10.18	Contract of Sale dated as of January 14, 2000 by and between Best Property Fund, L.P. and PRAECIS, as amended as of February 7, 2000 (1)
10.19	Acquisition and Construction Loan Agreement dated as of July 11, 2000 between 830 Winter Street LLC and Anglo Irish Bank Corporation plc and related Loan and Security Agreements (3)
10.20	Guaranty of Costs and Completion dated as of July 11, 2000 (3)
10.21	Guaranty of Non-Recourse Exceptions dated as of July 11, 2000 (3)
10.22	Environmental Compliance and Indemnity Agreement dated as of July 11, 2000 executed by 830 Winter Street LLC and PRAECIS (3)
10.23	Lease Agreement dated as of July 11, 2000 between 830 Winter Street LLC, as landlord, and PRAECIS, as tenant (3)
21.1	List of Subsidiaries of PRAECIS
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney (included on the signature page of this Report on Form 10-K)
31.1	Certification of Chief Executive Officer
31.2	Certification of Chief Financial Officer
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Represents a management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Registration Statement on Form S-1 (Registration No. 333-96351) initially filed with the Securities and Exchange Commission on February 8, 2000 and declared effective on April 26, 2000.

(2) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended March 31, 2000 filed with the Securities and Exchange Commission on June 7, 2000.

(3) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2000 filed with the Securities and Exchange Commission on August 14, 2000.

(4) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 filed with the Securities and Exchange Commission on November 13, 2000.

(5) Incorporated by reference to Registration Statement on Form S-1 (Registration No. 333-54342) initially filed with the Securities and Exchange Commission on January 26, 2001 and declared effective on February 14, 2001.

(6) Incorporated by reference to Registration Statement on Form 8-A filed with the Securities and Exchange Commission on January 26, 2001.

(7) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 filed with the Securities and Exchange Commission on May 8, 2002.

(8) Incorporated by reference to Registration Statement on Form S-8 (Registration No. 333-90734) filed with the Securities and Exchange Commission on June 18, 2002.

(9) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 filed with the Securities and Exchange Commission on August 12, 2002.

(10) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 filed with the Securities and Exchange Commission on November 13, 2002.

(11) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2002 filed with the Securities and Exchange Commission on March 19, 2003.

(12) Incorporated by reference to Registration Statement on Form S-8 (Registration No. 333-106012) filed with the Securities and Exchange Commission on June 11, 2003.

† Confidential treatment has been granted for certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(b) Reports on Form 8-K.

On October 24, 2003, we furnished a Current Report on Form 8-K to furnish under Item 12 (Results of Operations and Financial Condition) a copy of our Press Release dated October 24, 2003.

On November 19, 2003, we furnished a Current Report on Form 8-K to furnish under Item 9 (Regulation FD Disclosure) a copy of our Press Release dated November 19, 2003.

On November 26, 2003, we furnished a Current Report on Form 8-K to furnish under Item 9 (Regulation FD Disclosure) a copy of our Press Release dated November 26, 2003.

On December 10, 2003, we furnished a Current Report on Form 8-K to furnish under Item 9 (Regulation FD Disclosure) a copy of our Press Release dated December 10, 2003.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

PRAECIS PHARMACEUTICALS INCORPORATED

Date: March 15, 2004

By: /s/ KEVIN F. MCLAUGHLIN

Kevin F. McLaughlin
Chief Financial Officer, Executive Vice President, Treasurer and Secretary

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Malcolm L. Gefter and Kevin F. McLaughlin and each of them, as such person's true and lawful attorney-in-fact and agent with full power of substitution and revocation for such person and in such person's name, place and stead, in any and all capacities, to execute any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 15, 2004.

Signature	Title
/s/ MALCOLM L. GEFTER, PH.D. Malcolm L. Gefter, Ph.D.	Chairman of the Board and Chief Executive Officer *(Principal Executive Officer)*
/s/ KEVIN F. MCLAUGHLIN Kevin F. McLaughlin	Chief Financial Officer, Executive Vice President, Treasurer and Secretary *(Principal Financial and Accounting Officer)*
/s/ G. LEONARD BAKER, JR. G. Leonard Baker, Jr.	Director
/s/ GAREN G. BOHLIN Garen G. Bohlin	Director
/s/ HENRY F. MCCANCE Henry F. McCance	Director

Signature	Title
/s/ LEONARD E. POST, PH.D. Leonard E. Post, Ph.D.	Director
/s/ WILLIAM R. RINGO William R. Ringo	Director
/s/ DAVID B. SHARROCK David B. Sharrock	Director
/s/ PATRICK J. ZENNER Patrick J. Zenner	Director

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PRAECIS PHARMACEUTICALS INCORPORATED
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Report of Independent Auditors

Board of Directors and Stockholders
PRAECIS PHARMACEUTICALS INCORPORATED

We have audited the accompanying consolidated balance sheets of PRAECIS PHARMACEUTICALS INCORPORATED as of December 31, 2002 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of PRAECIS PHARMACEUTICALS INCORPORATED at December 31, 2002 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
January 23, 2004

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2002	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 64,913	$ 87,530
Marketable securities	130,122	55,662
Prepaid expenses and other assets	848	726
Total current assets	195,883	143,918
Property and equipment, net	71,252	67,713
Due from officer	933	833
Other assets	182	14
Total assets	$268,250	$212,478
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,285	$ 2,483
Accrued expenses	7,075	7,707
Current portion of long-term debt	—	747
Total current liabilities	10,360	10,937
Long-term debt	33,000	31,880
Commitments and contingencies		
Stockholders' equity:		
Common Stock, $0.01 par value; 200,000,000 shares authorized; 51,801,423 shares in 2002 and 52,011,002 shares in 2003 issued and outstanding	518	520
Additional paid-in capital	354,676	355,373
Accumulated other comprehensive income	203	73
Accumulated deficit	(130,507)	(186,305)
Total stockholders' equity	224,890	169,661
Total liabilities and stockholders' equity	$268,250	$212,478

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Statements of Operations
(In thousands, except per share data)

	Year Ended December 31,		
	2001	2002	2003
Corporate collaboration revenue	$ 9,907	$ 1,029	$ —
Costs and expenses:			
Research and development	59,416	56,383	41,907
Sales and marketing	8,737	1,837	5,234
General and administrative	6,961	9,676	10,006
Total costs and expenses	75,114	67,896	57,147
Operating loss	(65,207)	(66,867)	(57,147)
Interest income	10,503	6,113	2,508
Interest expense	(1,398)	(1,341)	(1,159)
Gain on assignment of leasehold improvements	1,499	—	—
Gain on termination of collaboration agreement	—	16,020	—
Net loss	$(54,603)	$(46,075)	$(55,798)
Net loss per share:			
Basic and diluted	$ (1.10)	$ (0.89)	$ (1.08)
Weighted average number of common shares:			
Basic and diluted	49,777	51,678	51,869

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2000	42,284,199	$423	$175,937		$ (29,829)	$146,531
Net loss					(54,603)	(54,603)
Unrealized gain on marketable securities				$ 730		730
Total comprehensive loss						(53,873)
Common Stock issued upon follow-on public offering (net of $10,476 in offering costs)	7,587,500	76	175,816			175,892
Stock compensation			(265)			(265)
Repurchase of Common Stock	(200,000)	(2)	(51)			(53)
Issuance of Common Stock	1,444,436	14	2,450			2,464
Balance at December 31, 2001	51,116,135	511	353,887	730	(84,432)	270,696
Net loss					(46,075)	(46,075)
Unrealized loss on marketable securities				(527)		(527)
Total comprehensive loss						(46,602)
Stock compensation			(185)			(185)
Issuance of Common Stock	685,288	7	974			981
Balance at December 31, 2002	51,801,423	518	354,676	203	(130,507)	224,890
Net loss					(55,798)	(55,798)
Unrealized loss on marketable securities				(130)		(130)
Total comprehensive loss						(55,928)
Stock compensation			148			148
Issuance of Common Stock	209,579	2	549			551
Balance at December 31, 2003	52,011,002	$520	$355,373	$ 73	$(186,305)	$169,661

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2001	2002	2003
Operating activities:			
Net loss	$ (54,603)	$ (46,075)	$ (55,798)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	3,500	4,704	4,551
Gain on assignment of leasehold improvements	(1,499)	—	—
Gain on termination of collaboration agreement	—	(16,020)	—
Stock compensation	(265)	(185)	148
Changes in operating assets and liabilities:			
Accounts receivable	621	458	—
Refundable income taxes	4,853	—	—
Unbilled revenues	1,493	—	—
Prepaid expenses and other assets	867	221	290
Due from officer	—	(933)	100
Accounts payable	17,887	(11,416)	(802)
Accrued expenses	566	(633)	632
Deferred revenue	(5,064)	—	—
Net cash used in operating activities	(31,644)	(69,879)	(50,879)
Investing activities:			
Purchase of available-for-sale securities	(177,110)	(137,220)	(41,009)
Sales and maturities of available-for-sale securities	56,309	128,102	115,339
Proceeds from disposition of property and equipment	1,499	—	—
Purchase of property and equipment	(23,879)	(1,756)	(1,012)
Net cash (used in) provided by investing activities	(143,181)	(10,874)	73,318
Financing activities:			
Follow-on public offering proceeds	175,892	—	—
Proceeds from debt issuance	9,000	—	—
Repayments of debt	—	—	(373)
Proceeds from the issuance of Common Stock, options and warrants	2,464	981	551
Repurchase of Common Stock	(53)	—	—
Net cash provided by financing activities	187,303	981	178
Increase (decrease) in cash and cash equivalents	12,478	(79,772)	22,617
Cash and cash equivalents at beginning of year	132,207	144,685	64,913
Cash and cash equivalents at end of year	$ 144,685	$ 64,913	$ 87,530

See accompanying notes.

1. Basis of Presentation

The Company

PRAECIS PHARMACEUTICALS INCORPORATED (the "Company") was incorporated in July 1993 under the laws of the State of Delaware. The Company is a drug discovery and development company engaged in the development of drugs for the treatment of human diseases.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the Company's accounts and the accounts of its wholly owned subsidiaries, 830 Winter Street LLC and PRAECIS Europe Limited. All significant intercompany account balances and transactions between the companies have been eliminated.

2. Significant Accounting Policies

Cash Equivalents

Cash equivalents consist principally of money market funds and other investments with original maturities of three months or less at the date of purchase.

Marketable Securities

The Company invests in marketable securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity. The Company has classified its marketable securities as "available-for-sale" and, accordingly, carries such securities at aggregate fair value. Unrealized gains and losses, if any, are reported as other comprehensive income in stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income and expense. The cost of securities sold is based on the specific identification method. Interest and dividends are included in interest income. At December 31, 2003, the Company's cash, cash equivalents and marketable securities had a maximum maturity of less than three years with an average maturity of approximately three months.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with high credit quality financial institutions and, by policy, limits its credit exposure to any one financial instrument, sovereignty or issuer.

2. Significant Accounting Policies (Continued)

Derivatives and Hedging

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, *Accounting for Derivative Instruments and Hedging Activities* ("SFAS No. 133"), and its amendments SFAS No. 137 and No. 138, in June 1999 and June 2000, respectively. SFAS No. 133 requires the Company to recognize all derivatives on the balance sheet at fair value. Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives are either offset against the change in fair value of assets, liabilities, or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. The ineffective portion of a derivative's change in fair value will be immediately recognized in earnings.

Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization are calculated using the straight-line method over the estimated useful life of the asset as follows:

Building	30 years
Building improvements	30 years or the remaining life of the building, whichever is shorter
Laboratory and office equipment	3–7 years or term of lease, whichever is shorter

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company reviews property, plant, and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of such an asset may not be recoverable. No revision to the estimated useful life or recorded amount of property and equipment was required.

Interest capitalized in connection with facilities is recorded as part of the asset to which it relates and is amortized over the asset's estimated useful life. Interest capitalized into construction in progress during 2001 was approximately $0.6 million.

Revenue Recognition

Revenue is deemed earned when all of the following have occurred: all obligations of the Company relating to the revenue have been met and the earning process is complete; the monies received or receivable are not refundable irrespective of research results; and there are neither future obligations nor future milestones to be met by the Company with respect to such revenue.

Corporate collaborations. Revenues are earned based upon research expenses incurred and milestones achieved. Non-refundable payments upon initiation of contracts are deferred and amortized over the period in which the Company is obligated to participate on a continuing and substantial basis in the research and development activities outlined in each contract. Amounts received in advance of reimbursable expenses are recorded as deferred revenue until the related expenses are incurred. Milestone payments are recognized as revenue in the period in which the parties agree that the milestone has been achieved and it is deemed that no further obligations exist.

Income Taxes

The Company provides for income taxes under SFAS No. 109, *Accounting for Income Taxes.* Under this method, deferred taxes are recognized using the liability method, whereby tax rates are applied to

2. Significant Accounting Policies (Continued)

cumulative temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes based on when and how they are expected to affect the tax return.

Research and Development

Research and development costs, including those associated with technology, licenses and patents, are expensed as incurred. Research and development costs include primarily costs related to ongoing clinical programs, manufacturing and materials inventory costs, salaries, lab supplies and other fixed facility costs used in the Company's research and development operations.

Stock-Based Compensation

The Company has elected to follow Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), in accounting for its stock-based employee compensation plans using the intrinsic value method, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"), as SFAS No. 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB No. 25, when the exercise price of options granted to employees under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required.

The reconciliation of net loss and net loss per share, as reported, to pro forma net loss and net loss per share giving effect to employee stock-based compensation accounted for using the fair value accounting method, is as follows:

	Year Ended December 31,		
	2001	2002	2003
		(in thousands)	
Net loss, as reported	$(54,603)	$(46,075)	$(55,798)
Deduct/(add): Stock compensation cost as computed under APB No. 25	(265)	(185)	148
Deduct: Stock based employee compensation cost, net of related tax effects, that would have been included in the determination of net loss as reported if the fair value method had been applied to all awards	(7,847)	(10,792)	(10,136)
Pro forma net loss	$(62,715)	$(57,052)	$(65,786)
Diluted net loss per share, as reported	$ (1.10)	$ (0.89)	$ (1.08)
Diluted net loss per share, pro forma	$ (1.26)	$ (1.10)	$ (1.27)

The fair value of the stock options at the date of grant was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	2001	2002	2003
Risk-free interest rate	4.0%	4.0%	4.0%
Expected life (years)	5	6	6
Volatility	84%	103%	84%

2. Significant Accounting Policies (Continued)

The Company has never declared or paid any cash dividends on any of its capital stock and does not expect to do so in the foreseeable future.

Accounting Pronouncements

On December 31, 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure* ("SFAS No. 148"). SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting* ("APB No. 28"), to include increased pro-forma disclosure of the effects of stock-based employee compensation on the results of operations. SFAS No. 148 became effective for fiscal years ending after December 15, 2002. The Company has elected to continue to account for employee stock-based compensation using the intrinsic value method as described in APB No. 25 and therefore, the adoption of SFAS No. 148 did not have a material impact on the Company's consolidated results of operations in 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities* ("FIN No. 46"). FIN No. 46 sets forth the criteria used in determining whether an investment in a variable interest entity ("VIE"), should be consolidated and is based on the general premise that companies that control another entity through interests other than voting interests should consolidate the controlled entity. The Company does not have any VIE's. Accordingly, the implementation of FIN No. 46 will not have any impact on the Company's consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS No. 150"). SFAS No. 150 establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies. The FASB has indefinitely deferred implementation of some provisions of SFAS No. 150. The Company believes that the adoption of SFAS No. 150 will not have a material impact on the Company's consolidated financial statements.

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains or losses on marketable securities and is reflected in the consolidated statements of stockholders' equity.

Net Loss Per Share

Basic net loss per share is based on the weighted average number of shares of common stock, par value $.01 per share ("Common Stock") outstanding. For all years presented, diluted net loss per common share is the same as basic net loss per common share as the inclusion of Common Stock equivalents, including the effect of stock options and warrants, would be antidilutive due to the Company's net loss position for all periods presented.

3. Marketable Securities

The Company's marketable securities, which are classified as available-for-sale, are as follows (in thousands):

	December 31, 2003			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies:				
Due in one year or less	$ 5,126	$ 14	$ —	$ 5,140
Due in one to three years	10,068	17	—	10,085
U.S. corporate securities:				
Due in one year or less	8,766	—	(9)	8,757
Due in one to three years	31,629	77	(26)	31,680
Total marketable securities	$55,589	$108	$(35)	$55,662

	December 31, 2002			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies:				
Due in one year or less	$ 3,089	$ 10	$ —	$ 3,099
Due in one to three years	33,999	140	(2)	34,137
U.S. corporate securities:				
Due in one year or less	31,153	158	(109)	31,202
Due in one to three years	61,678	54	(48)	61,684
Total marketable securities	$129,919	$362	$(159)	$130,122

4. Due from Officer

In May 2002, the Company extended a $1.0 million loan to an officer in connection with the officer's acceptance of employment with the Company. The loan is full recourse, uncollateralized, bears no interest and becomes due and payable in May of 2012. Under the terms of the promissory note (the "Note") executed in connection with the loan, 10% of the original loan principal will be forgiven annually on each anniversary date of the Note, provided that the officer remains an employee of the Company. The Company is not responsible for the personal income tax implications related to the forgiveness of this Note. Upon the officer's voluntary termination of employment with the Company, with certain exceptions, and upon termination by the Company of the officer's employment for cause, the Note becomes immediately due and payable.

5. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2002	2003
	(in thousands)	
Building	$56,784	$57,010
Land	10,500	10,500
Laboratory and office equipment	15,306	16,384
Construction in progress	292	—
	82,882	83,894
Less: accumulated depreciation and amortization	11,630	16,181
	$71,252	$67,713

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2002	2003
	(in thousands)	
Clinical trial costs	$2,644	$2,642
Accrued compensation	1,357	1,833
Unvouchered invoices	683	1,054
Other	2,391	2,178
	$7,075	$7,707

7. Stockholders' Equity

Public Offerings

In February 2001, the Company completed a follow-on public offering of its Common Stock. The Company sold 7,587,500 shares of Common Stock resulting in net proceeds to the Company of approximately $175.9 million.

Convertible Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue 200,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, par value $.01 per share ("Preferred Stock"). The Preferred Stock is issuable in one or more classes or series, each of such classes or series to have such rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as may be determined by the Board of Directors. No shares of Preferred Stock have been issued.

7. Stockholders' Equity (Continued)

Rights Plan

In January 2001, the Company adopted a Rights Agreement (the "Rights Agreement"), commonly known as a "poison pill." Under the Rights Agreement, the Company distributed certain rights to acquire shares of the Company's Series A junior participating preferred stock (the "Rights") as a dividend for each share of Common Stock held of record as of February 5, 2001. Each share of Common Stock issued after the February 5, 2001 record date has an attached Right. Under certain conditions involving an acquisition by any person or group of 10% or more of the Common Stock, each Right permits the holder (other than the 10% holder) to purchase Common Stock having a value equal to twice the exercise price of the Right, upon payment of the exercise price of the Right. In addition, in the event of certain business combinations after an acquisition by a person or group of 10% or more of the Common Stock, each Right entitles the holder (other than the 10% holder) to receive, upon payment of the exercise price, Common Stock having a value equal to twice the exercise price of the Right. The Rights have no voting privileges and, unless and until they become exercisable, are attached to, and automatically trade with, the Company's Common Stock. The Rights will terminate upon the earlier of the date of their redemption or ten years from the date of issuance.

Employee Stock Purchase Plan

Under the Company's Amended and Restated Employee Stock Purchase Plan (the "ESPP") eligible employees may purchase shares of Common Stock at a price per share equal to 85% of the lower of the fair market value per share of the Common Stock at the beginning or the end of each six month period during the term of the ESPP. Participation is limited to the lesser of 10% of the employee's compensation or $25,000 in any calendar year. On March 13, 2003, the Board of Directors approved an amendment to the ESPP extending the term of this plan through 2005 and increasing the number of shares authorized for issuance from 160,000 to 400,000, subject to stockholder approval. In May 2003, the stockholders of the Company approved this amendment. During 2001, 2002 and 2003, the Company issued 35,532, 53,571 and 55,866 shares of Common Stock, respectively, under the ESPP.

Stock Option Plan

The Second Amended and Restated 1995 Stock Plan, as amended (the "Plan"), allows for the granting of incentive and nonqualified options and awards to purchase shares of Common Stock. Incentive options granted to employees under the Plan generally vest at 20% on the first anniversary of the date of grant, with the remaining shares vesting equally over four years following such anniversary date. Nonqualified options issued to consultants under the Plan generally vest over the period of service with the Company. At December 31, 2003, a total of 14,375,000 shares of Common Stock were approved for issuance under the Plan.

7. Stockholders' Equity (Continued)

Information regarding options under the Plan is summarized below (in thousands, except per share data):

	2001		2002		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at January 1,	8,235	$6.74	6,659	$8.54	7,061	$7.82
Granted	1,087	11.75	1,779	3.30	1,596	5.15
Exercised	(1,209)	1.74	(632)	1.31	(154)	2.39
Cancelled	(1,454)	6.38	(745)	9.07	(146)	9.14
Options outstanding at December 31,	6,659	$8.54	7,061	$7.82	8,357	$7.33
Options exercisable at December 31,	3,274	$4.73	3,330	$6.70	4,632	$6.82

The weighted average per share fair value of options granted was $10.05 in 2001, $2.75 in 2002, and $3.70 in 2003. At December 31, 2003, there were 10,090,370 shares of Common Stock reserved for the exercise of stock options and for issuances under the ESPP, including 1,487,759 options available for future grant under the Plan.

The following table presents weighted average exercise price and weighted average remaining contractual life information about significant option groups outstanding at December 31, 2003 (option amounts in thousands):

Exercise Price	Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
$0.13–$1.60	1,150	2.6	$ 0.54	968	$ 0.59
$1.61–$6.38	4,699	6.9	$ 4.41	2,547	$ 4.64
$6.39–$16.25	1,562	7.7	$ 9.66	672	$11.40
$16.26–$42.00	947	6.9	$26.23	445	$25.94
	8,357			4,632	

On October 3, 2001, an executive officer of the Company exercised an option to purchase 200,000 shares of Common Stock at an exercise price of $0.27 per share. On November 30, 2001, this option exercise was rescinded, and accordingly, the officer returned to the Company the 200,000 shares of Common Stock acquired upon the exercise of the option, the Company returned to the officer the option exercise price and the option to purchase 200,000 shares of Common Stock was restored. During 2001, the Company recognized approximately $256,000 in compensation expense related to this transaction.

8. Income Taxes

The Company has reported no income tax provision or benefit in 2001, 2002 or 2003 due to the significant net operating losses in these years as well as limitations on the recognition of deferred tax assets for financial reporting purposes.

8. Income Taxes (Continued)

A reconciliation of the Company's income tax provision to the statutory federal provision is as follows:

	Year Ended December 31,		
	2001	2002	2003
		(in thousands)	
Statutory federal income tax benefit	$(18,565)	$(15,614)	$(18,971)
Increase in valuation allowance	18,565	15,570	18,921
Other	—	44	50
Income tax provision	$ —	$ —	$ —

Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2002	2003
	(in thousands)	
Deferred tax assets:		
Net operating losses	$51,943	$69,531
Property and equipment	2,651	9,793
Accrued expenses	1,813	1,066
Research and development tax credits	7,640	5,953
Other	74	113
Total deferred tax assets	64,121	86,456
Valuation allowance	(64,121)	(86,456)
	$ —	$ —

At December 31, 2002 and 2003, the Company has provided a valuation allowance for the value of the deferred tax assets. The valuation allowance increased by $21.6 million in 2002 and $22.3 million in 2003 due primarily to the increase in net operating losses and tax credit carryforwards. The Company has federal net operating loss carryforwards in the amount of approximately $170.3 million, which expire through 2023. Due to anticipated operating losses in the future, the Company believes that it is more likely than not that it will not realize the net deferred tax assets in the future and has provided an appropriate valuation allowance.

Any subsequent recognized tax benefits relating to a reduction in the valuation allowance for deferred tax assets as of December 31, 2003 would be allocated as follows (in thousands):

Reported in the statement of operations	$81,688
Reported in additional paid-in capital	4,768
	$86,456

9. Corporate Collaborations

Sanofi-Synthélabo Agreement

In May 1997, the Company entered into a license agreement with Synthélabo S.A., which subsequently merged with Sanofi S.A. forming Sanofi-Synthélabo S.A. ("Sanofi-Synthélabo"), for the

9. Corporate Collaborations (Continued)

development and commercialization of the Company's Plenaxis products. Upon initiation, the Company received a one-time, non-refundable payment of $4.7 million. This initiation fee was recognized into revenue through 2001, which was the period during which the Company was obligated under the agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development activities.

In October 2001, Sanofi-Synthélabo notified the Company that it was terminating the Sanofi-Synthélabo agreement effective December 31, 2001. As a result of the termination of the Sanofi-Synthélabo agreement, all licenses for Plenaxis granted to Sanofi-Synthélabo under the agreement, and all rights of Sanofi-Synthélabo in the Plenaxis program, have terminated. In addition, in connection with the termination of the Sanofi-Synthélabo agreement, the Company received in 2002 a final reimbursement payment from Sanofi-Synthélabo of approximately $1.0 million for collaboration expenses incurred by the Company.

The Company recognized revenues in 2001, 2002 and 2003 of approximately $2.1 million, $1.0 million and zero, respectively, under the Sanofi-Synthélabo agreement.

Amgen Agreement

In March 1999, the Company entered into a binding agreement in principle (the "License Agreement") with Amgen Inc. ("Amgen") for the development and commercialization of the Company's Plenaxis products. In accordance with the License Agreement, the Company received from Amgen a $10.0 million, one-time, non-refundable payment upon initiation. This initiation fee was recognized into revenue through 2001, which was the period during which the Company was obligated under the License Agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development activities. In addition to the signing payment, Amgen paid the first $175.0 million of all authorized costs and expenses associated with the development and commercialization of Plenaxis products, including the cost of materials, in the United States. Following Amgen's completion of this funding during the third quarter of 2000, the Company became responsible for one-half of all subsequent United States research and development costs for Plenaxis products through the launch period. Additionally, the Company was to reimburse Amgen for one-half of the costs associated with establishing a sales and marketing infrastructure for Plenaxis products in the United States.

In September 2001, Amgen notified the Company that it was terminating the License Agreement effective December 17, 2001. As a result of the termination of the License Agreement, all licenses for Plenaxis granted to Amgen under the License Agreement, and all rights of Amgen in the Plenaxis program, have terminated. At that time, the Company accrued an estimate of its potential liability of approximately $29.1 million under the License Agreement.

In 2002, the Company assumed all of Amgen's rights and obligations under the Development and Supply Agreement with UCB S.A. ("UCB") and finalized a termination agreement with respect to the termination by Amgen of the License Agreement (the "Termination Agreement"). Under the terms of the Termination Agreement, the Company paid to Amgen $13.0 million in full and complete satisfaction of all amounts payable under the License Agreement and in consideration of the transfer from Amgen to the Company of title to, and possession of, any existing materials inventory. As a result, the Company recognized a gain of $16.0 million during the third quarter of 2002.

The Company recognized revenues in 2001, 2002 and 2003 of approximately $7.8 million, zero and zero, respectively, under the Amgen agreement.

10. Building and Related Mortgage Financing

In July 2000, in connection with the purchase of the Company's corporate headquarters and research facility in Waltham, Massachusetts for approximately $41.3 million, the Company's wholly owned real estate subsidiary entered into an acquisition and construction loan agreement providing for up to $33.0 million in financing for the acquisition of, and improvements to, the facility. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.12% at December 31, 2003). Principal and interest are payable monthly in arrears. In July 2003, the Company exercised the first of two one-year extension options, extending the maturity date of the loan until July 30, 2004. As a result of this extension, in 2003 the Company started making monthly principal payments on the loan of approximately $62,000, in addition to interest payments. Principal payments are being amortized over a 25-year term. Principal is due and payable in full on July 30, 2004, subject to a one-year extension option, exercisable at the Company's option. Since the Company has the ability and intent to exercise the extension option to extend the maturity date until July 30, 2005, the loan has been classified as long-term debt in the accompanying consolidated balance sheet. The loan is secured by the facility, together with all fixtures, equipment, improvements and other related items, and by all rents, income or profits received by the Company's real estate subsidiary and is unconditionally guaranteed by the Company. The Company occupied this facility during May 2001 and may sublease a portion of the facility.

The Company has entered into an interest rate cap agreement (the "Interest Rate Cap Agreement") in order to reduce the potential impact of interest rate increases on future income. At December 31, 2003, the notional amount and fair market value under the Interest Rate Cap Agreement were $32.6 million and zero, respectively. Interest paid under the loan agreement approximated interest expense in 2001, 2002 and 2003.

During September 2001, the Company terminated the lease for, and all future obligations with respect to, its Cambridge, Massachusetts facility and recorded a gain. In October 2001, the Company assigned to a third party the Company's right, title and interest in and to the Company's lease for its New Jersey facility and the third party has assumed all obligations thereunder.

11. Commitments

Indiana University Foundation ("IUF") License Agreement

The Company has a license agreement with IUF, which was assigned by IUF to IUF's Advanced Research and Technology Institute, Inc., with respect to rights to Plenaxis and certain related technology. In exchange for the license, the Company agreed to pay (a) fees of $0.3 million, (b) up to an additional $4.3 million upon achievement of specific milestones and (c) a royalty percentage of net sales of licensed products, if any. The Company made milestone payments of $1.0 million in 2003 under the IUF agreement. As of December 31, 2003, $2.5 million in milestones remained subject to future achievement.

Baxter Pharmaceutical Solutions LLC ("Baxter")

On December 4, 2002, the Company signed a five-year commercial supply agreement (the "Baxter Agreement") with Baxter related to the fill and finish steps of the manufacturing process for Plenaxis. Under the terms of the Baxter Agreement, the Company is required to purchase a minimum of $375,000 of product from Baxter during 2004. In January 2005, the first anniversary of the first commercial shipment of Plenaxis, the minimum annual purchase commitment will increase to $650,000. The Company made payments of approximately $1.8 million in 2003 under the Baxter Agreement.

11. Commitments (Continued)

Cambrex Charles City, Inc. ("Cambrex")

In July 1998, the Company entered into a seven-year supply agreement with Cambrex (formerly Salsbury Chemicals, Inc.). Under this agreement, Cambrex has agreed to manufacture for us the commercial depot formulations of Plenaxis. The Company contributed approximately $6.0 million toward Cambrex's construction and outfitting of a dedicated manufacturing facility. The Company retains all rights to manufacturing technology developed in connection with this agreement. During 2003, the Company paid Cambrex approximately $632,000 toward minimum purchase commitments and facility maintenance and its minimum purchase commitment for 2004 is $792,000.

STOCKHOLDER INFORMATION

BOARD OF DIRECTORS

Malcolm L. Gefter, Ph.D.
Chairman and
Chief Executive Officer,
PRAECIS

G. Leonard Baker, Jr.
Managing Director,
Sutter Hill Ventures,
a venture capital firm

Garen G. Bohlin
President and
Chief Executive Officer,
Syntonix Pharmaceuticals, Inc.,
a biotechnology company

Henry F. McCance
Chairman and President,
Greylock Management
Corporation,
a venture capital firm

Leonard E. Post, Ph.D.
Senior Vice President,
Research and Development,
Onyx Pharmaceuticals, Inc.,
a biotechnology company

William R. Ringo
Consultant, retired President,
Oncology and Critical Care,
Eli Lilly and Company, a global
pharmaceutical company

David B. Sharrock
Consultant, retired Executive
Vice President and Chief
Operating Officer, Marion
Merrell Dow Inc., a global
pharmaceutical company

Patrick J. Zenner
Retired President and
Chief Executive Officer,
Hoffmann-LaRoche Inc.,
North America, a global
pharmaceutical company

EXECUTIVE OFFICERS

Malcolm L. Gefter, Ph.D.
Chairman and
Chief Executive Officer

William K. Heiden
President and
Chief Operating Officer

Kevin F. McLaughlin
Executive Vice President,
Chief Financial Officer,
Treasurer and Secretary

Marc B. Garnick, M.D.
Executive Vice President and
Chief Medical Officer

Richard W. Wagner, Ph.D.
Executive Vice President,
Discovery Research

INDEPENDENT AUDITORS

Ernst & Young LLP
Boston, Massachusetts

CORPORATE COUNSEL

Skadden, Arps, Slate,
Meagher & Flom LLP
Boston, Massachusetts

INVESTOR RELATIONS

PRAECIS invites stockholders, security analysts, representatives of portfolio management firms and other interested parties to contact:

Kevin F. McLaughlin
Executive Vice President,
Chief Financial Officer,
Treasurer and Secretary
PRAECIS PHARMACEUTICALS
INCORPORATED
830 Winter Street
Waltham, Massachusetts 02451-1420
781.795.4100

CORPORATE HEADQUARTERS

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www.praecis.com

TRANSFER AGENT AND REGISTRAR

The transfer agent is responsible, among other things, for handling stockholder questions regarding lost stock certificates, address changes, including duplicate mailings, and changes in ownership or name in which shares are held. These requests may be directed to the transfer agent at the following address:

American Stock Transfer &
Trust Company
59 Maiden Lane, Plaza Level
New York, New York 10038
800.937.5449
www.amstock.com

ANNUAL MEETING

The Annual Meeting of Stockholders will be held at 10:00 a.m. on Thursday, May 13, 2004 at:

PRAECIS PHARMACEUTICALS
INCORPORATED
830 Winter Street
Waltham, Massachusetts 02451-1420

FORM 10-K

A copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, including the financial statements, and excluding exhibits, is included as part of this Annual Report. Copies of the Form 10-K, exclusive of exhibits, are available without charge by contacting Investor Relations at 781.795.4100, sending an e-mail message to info@praecis.com, or sending a written request to:

Investor Relations
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